

Exhibit 23

Confidential Subject to Protective Order

1 UNITED STATES DISTRICT COURT
2 SOUTHERN DISTRICT OF NEW YORK

3 IN RE: ACETAMINOPHEN -) MDL No. 3043
4 ASD-ADHD PRODUCTS)
5 LIABILITY LITIGATION) Case No.
6) 1:22-md-03043-DLC
7 THIS DOCUMENT RELATES TO:)
8) JUDGE DENISE
9 All Cases, 1:22-md-03043) COTE

10
11 WEDNESDAY, AUGUST 9, 2023

12 CONFIDENTIAL - PURSUANT TO PROTECTIVE ORDER

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14 Videotaped deposition of Eric
15 Hollander, M.D. DFAPA, FACNP, held at the
16 Lanier Law Firm, 126 East 56th Street,
17 New York, New York, commencing at 9:43 a.m.
18 Eastern, on the above date, before Carrie A.
19 Campbell, Registered Diplomate Reporter,
20 Certified Realtime Reporter, Illinois,
21 California & Texas Certified Shorthand
22 Reporter, Missouri, Kansas, Louisiana & New
23 Jersey Certified Court Reporter.

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<p>Page 11</p> <p>1 VIDEOGRAPHER: We are now on</p> <p>2 the record. My name is Danny Ortega,</p> <p>3 and I'm the legal videographer for</p> <p>4 Golkow Litigation Services.</p> <p>5 Today's date is August 9, 2023,</p> <p>6 and the time is 9:43 a.m.</p> <p>7 This video deposition is being</p> <p>8 held at 126 East 56th Street,</p> <p>9 New York, New York, in the matter of</p> <p>10 Acetaminophen (Tylenol) ASD-ADHD</p> <p>11 Products Liability Litigation.</p> <p>12 The deponent today is Eric</p> <p>13 Hollander.</p> <p>14 All counsel will be noted on</p> <p>15 the stenographic record.</p> <p>16 The court reporter today is</p> <p>17 Carrie Campbell and will now swear in</p> <p>18 the witness.</p> <p>19</p> <p>20 ERIC HOLLANDER, M.D. DFAPA, FACNP,</p> <p>21 of lawful age, having been first duly sworn</p> <p>22 to tell the truth, the whole truth and</p> <p>23 nothing but the truth, deposes and says on</p> <p>24 behalf of the Defendant Johnson & Johnson, as</p> <p>25 follows:</p>	<p>Page 12</p> <p>1 examination of Dr. Cabrera?</p> <p>2 A. Yes.</p> <p>3 Q. Okay. When were you provided</p> <p>4 that?</p> <p>5 A. Prior to this deposition.</p> <p>6 Q. And when? Today? A week ago?</p> <p>7 Two days ago?</p> <p>8 A. Sometime between, I believe,</p> <p>9 when I filed my rebuttal and when we're</p> <p>10 meeting today.</p> <p>11 Q. Okay. And if I understood you,</p> <p>12 you chose not to review it; is that right?</p> <p>13 A. I didn't review it. I didn't</p> <p>14 have time to review it.</p> <p>15 Q. Okay. Did you skim it?</p> <p>16 A. No.</p> <p>17 Q. Did you open it at all?</p> <p>18 A. No.</p> <p>19 Q. Okay. Is there any opinion --</p> <p>20 well, let me lay some foundation here.</p> <p>21 You offered a rebuttal report</p> <p>22 in this litigation, right?</p> <p>23 A. That's correct.</p> <p>24 Q. And an initial report?</p> <p>25 A. Yes.</p>

<p>Page 14</p> <p>1 Q. And an amended -- well, an 2 initial report and an amended report and a 3 rebuttal report, right? 4 A. Right. And an amended 5 causation report and a rebuttal report. 6 Q. Okay. And is there anything as 7 a result of Dr. Cabrera's testimony here that 8 you want to change in your three reports that 9 you've issued? 10 A. No. 11 Q. So you, sitting here today, 12 have no idea what happened or didn't happen 13 or said or was said at Dr. Cabrera's 14 deposition; is that fair? 15 A. I think it's fair. I haven't 16 reviewed the deposition. 17 Q. Okay. Your counsel handed me a 18 paper before we started today. 19 Did you see him do that? 20 A. Yes, I did. 21 Q. Okay. And is this something 22 that you reviewed? 23 A. Yes. 24 (Hollander Exhibit 50 marked 25 for identification.)</p>	<p>Page 16</p> <p>1 enough there in that paper on the Notch or 2 SOX pathway to influence his causation 3 opinion? 4 MR. DOVEL: Objection. Form. 5 THE WITNESS: I'm not aware of 6 whether or not he made that statement. 7 QUESTIONS BY MR. MURDICA: 8 Q. Okay. Dr. Cabrera -- I mean, 9 sorry, Dr. Hollander, are you, sitting here 10 today, going to tell us that the Notch 11 signaling or SOX pathway is a biologically 12 plausible mechanism that you are going to 13 rely on for your opinions here relating to 14 acetaminophen and the outcomes of ASD and 15 ADHD? 16 A. Well, it's not a pathway that I 17 considered in my amended expert report or in 18 my rebuttal report, but it's additional 19 information that supports my opinions with 20 regards to exposure and outcome. 21 Q. Okay. Dr. Hollander, have you 22 ever, in your regular work, researched Notch 23 signaling? 24 A. No. 25 Q. Okay. In your regular work,</p>
<p>Page 15</p> <p>1 QUESTIONS BY MR. MURDICA: 2 Q. Okay. I'm going to mark it for 3 the sake of the record as Exhibit 51. 50. 4 Do you recognize this, 5 Dr. Hollander, as what was handed to me 6 before we started? 7 A. Yes, I recognize it. 8 Q. Okay. Are you relying on 9 Exhibit 50 for -- to support your causation 10 opinions here? 11 MR. DOVEL: Objection. Form. 12 QUESTIONS BY MR. MURDICA: 13 Q. Dr. Hollander, I'll ask a new 14 question. 15 Are you relying on Exhibit 50 16 for any opinion you have here? 17 MR. DOVEL: Objection. Form. 18 THE WITNESS: I'm incorporating 19 this material, along with all of the 20 other material that I have from my 21 materials considered, and it is 22 consistent with my opinion. 23 QUESTIONS BY MR. MURDICA: 24 Q. Okay. Dr. Hollander, do you 25 know that Dr. Cabrera said that there's not</p>	<p>Page 17</p> <p>1 have you ever done any research or 2 experimentation regarding the SOX2 pathway? 3 A. No. 4 Q. Okay. In your expert report, 5 did you identify the hippocampus as an area 6 of the brain that is related to the 7 underlying development of ASD or ADHD? 8 A. Well, yes. The hippocampus is 9 a, you know, essential region that's involved 10 in learning and memory that plays a critical 11 role across neurodevelopmental disorders, and 12 that can be disrupted by exposure that 13 affects neurodevelopment. 14 Q. Okay. The study that you have 15 in front of you, Exhibit 50, doesn't say 16 anything about ASD or ADHD, correct? 17 A. No, I don't see the words "ASD" 18 or "ADHD" in the abstract. 19 Q. And it's a study of mice, 20 correct? 21 A. That's correct. 22 Q. When did you review that, 23 Exhibit 50? 24 A. Over the weekend. 25 Q. Okay. And if Dr. Cabrera is</p>

<p style="text-align: right;">Page 18</p> <p>1 not relying on that for his opinion, that</p> <p>2 doesn't change what you're doing with respect</p> <p>3 to it, correct?</p> <p>4 MR. DOVEL: Objection. Form.</p> <p>5 THE WITNESS: Whether or not he</p> <p>6 relies on this specific article for</p> <p>7 his opinion, what I said before holds</p> <p>8 true, that it's a piece of evidence</p> <p>9 that I've reviewed that is supportive</p> <p>10 of my opinions.</p> <p>11 QUESTIONS BY MR. MURDICA:</p> <p>12 Q. Okay. In your -- so,</p> <p>13 Dr. Hollander, your regular job is counseling</p> <p>14 patients who have primarily OCD and autism,</p> <p>15 correct?</p> <p>16 MR. DOVEL: Objection. Form.</p> <p>17 THE WITNESS: Well, I'm not</p> <p>18 sure what you mean by "regular job,"</p> <p>19 but, you know, among my different</p> <p>20 roles, one of my activities is, yes,</p> <p>21 I'm involved in clinical care of</p> <p>22 patients with ASD and ADHD and OCD and</p> <p>23 other neurodevelopmental and</p> <p>24 psychiatric disorders.</p> <p>25</p>	<p style="text-align: right;">Page 20</p> <p>1 technical issue.</p> <p>2 Are you ready to proceed?</p> <p>3 A. Yes, I am.</p> <p>4 Q. Okay. When we stopped for the</p> <p>5 technical issue, I was asking about your</p> <p>6 testimony here versus your regular day-to-day</p> <p>7 job.</p> <p>8 Do you remember that question?</p> <p>9 A. Yes, I do.</p> <p>10 Q. Okay. And you testified that</p> <p>11 you have in the past testified for</p> <p>12 plaintiffs' lawyers, correct?</p> <p>13 A. That is correct.</p> <p>14 Q. Right.</p> <p>15 And you offered opinions while</p> <p>16 being paid for plaintiffs' lawyers in the</p> <p>17 Mirapex litigation; is that right?</p> <p>18 A. Well, that's correct. I</p> <p>19 offered opinions in the Mirapex litigation,</p> <p>20 and I was compensated for my time.</p> <p>21 Q. You offered opinions while</p> <p>22 being paid by plaintiffs' lawyers in the</p> <p>23 Abilify litigation; is that correct?</p> <p>24 A. That's correct. I offered</p> <p>25 opinions in the Abilify litigation as well</p>
<p style="text-align: right;">Page 19</p> <p>1 QUESTIONS BY MR. MURDICA:</p> <p>2 Q. Yeah.</p> <p>3 Dr. Hollander, what I meant is,</p> <p>4 your regular day-to-day job does not normally</p> <p>5 entail testifying for plaintiffs' lawyers in</p> <p>6 depositions, right?</p> <p>7 A. I have been involved in</p> <p>8 testifying for plaintiffs' lawyers as part of</p> <p>9 the various roles that I've been involved in.</p> <p>10 I wouldn't say I do that on a day-to-day</p> <p>11 basis, but that is an activity that I have</p> <p>12 done as part of my overall activities.</p> <p>13 MR. MURDICA: I guess we have a</p> <p>14 tech issue.</p> <p>15 Do I understand that correctly?</p> <p>16 MS. JOHNSTON: Let's off the</p> <p>17 record for a sec.</p> <p>18 VIDEOGRAPHER: Yeah, the time</p> <p>19 is 9:51 a.m. We are off the record.</p> <p>20 (Off the record at 9:51 a.m.)</p> <p>21 VIDEOGRAPHER: The time right</p> <p>22 now is 9:56 a.m. We are back on the</p> <p>23 record.</p> <p>24 QUESTIONS BY MR. MURDICA:</p> <p>25 Q. Dr. Hollander, there was a</p>	<p style="text-align: right;">Page 21</p> <p>1 and was compensated for my time.</p> <p>2 Q. Okay. Have you taken money</p> <p>3 from the plaintiffs' Bar to offer testimony</p> <p>4 in any other cases between Abilify and this</p> <p>5 one?</p> <p>6 MR. DOVEL: Objection. Form.</p> <p>7 THE WITNESS: I don't believe</p> <p>8 so.</p> <p>9 QUESTIONS BY MR. MURDICA:</p> <p>10 Q. Okay. Do you disclose to your</p> <p>11 patients that you've taken money from the</p> <p>12 plaintiffs' Bar?</p> <p>13 MR. DOVEL: Objection. Form.</p> <p>14 THE WITNESS: Well, I don't</p> <p>15 believe that I have a discussion with</p> <p>16 each of my patients if -- if the</p> <p>17 interactions that I'm having with my</p> <p>18 patients have any relevance to the</p> <p>19 testimony, for example, that I've</p> <p>20 offered. So, no.</p> <p>21 QUESTIONS BY MR. MURDICA:</p> <p>22 Q. Okay. Dr. Hollander, you've</p> <p>23 published papers before, right?</p> <p>24 A. Yes, I have.</p> <p>25 Q. In the disclosure section, do</p>

<p style="text-align: right;">Page 22</p> <p>1 you include that you've taken hundreds of 2 thousands of dollars from the plaintiffs' 3 Bar? 4 MR. DOVEL: Objection. Form. 5 THE WITNESS: In articles that 6 I publish, I disclose if there are 7 relevant conflicts of interest. 8 QUESTIONS BY MR. MURDICA: 9 Q. Okay. So the answer to my 10 question is, to date, you haven't disclosed 11 in any article that you've published that 12 you've taken hundreds of thousands of dollars 13 from the plaintiffs' Bar in the United 14 States, correct? 15 MR. DOVEL: Objection. Form. 16 THE WITNESS: I don't believe 17 that there has been an occasion where 18 I've published material where that 19 would be a relevant conflict of 20 interest to disclose. 21 QUESTIONS BY MR. MURDICA: 22 Q. And, therefore, you haven't 23 done it to date, correct? 24 A. Well, if I -- if I were to 25 publish and it was relevant to compensation</p>	<p style="text-align: right;">Page 24</p> <p>1 would require a disclosure {sic} related to 2 that because I don't believe that I've 3 published anything that would be related to 4 material that I testified on. 5 Q. You maintain a website called 6 Spectrum Neurosciences, correct? 7 A. That's one of the websites that 8 I maintain, correct. 9 Q. Do you have a disclosure on 10 there about the money that you've taken from 11 the plaintiffs' Bar? 12 MR. DOVEL: Objection. Form. 13 THE WITNESS: I don't believe 14 that there is anything on that website 15 that relates to any material, 16 actually, that would relate to 17 testimony in any products liability 18 case, no. 19 QUESTIONS BY MR. MURDICA: 20 Q. Dr. Hollander, have you ever 21 published anything on acetaminophen? 22 A. I don't believe that I've 23 published anything on acetaminophen. 24 Q. Dr. Hollander, have you ever 25 conducted any research regarding</p>
<p style="text-align: right;">Page 23</p> <p>1 that I've received -- and this would be the 2 case whether it was compensation related to, 3 you know, research grants or consulting 4 activities or speaking or testimony -- then I 5 would disclose the relevant conflict. 6 Q. Okay. And, Dr. Hollander, have 7 you ever disclosed as a relevant conflict 8 money you've taken from the plaintiffs' Bar? 9 A. I don't believe that I've 10 published any material that would be relevant 11 to the issues, for example, that I've offered 12 opinion on and, therefore, I wouldn't be 13 bound to disclose because it wouldn't have 14 been a conflict of interest. 15 Q. And therefore, Dr. Hollander, 16 your testimony is you haven't done it because 17 it hasn't been necessary, in your opinion, 18 correct? 19 MR. DOVEL: Objection. Form. 20 THE WITNESS: Well, that -- 21 that's correct. I don't believe that 22 I've -- 23 QUESTIONS BY MR. MURDICA: 24 Q. Okay. 25 A. -- published anything where it</p>	<p style="text-align: right;">Page 25</p> <p>1 acetaminophen prior to your engagement in 2 this litigation? 3 A. I don't believe that I've been 4 involved in prior research with 5 acetaminophen. 6 Q. Have you conducted any animal 7 studies with respect to acetaminophen? 8 A. No. 9 Q. Have you ever conducted animal 10 studies at all, Dr. Hollander? 11 A. Yes. 12 Q. Okay. And was it you 13 conducting them or supervising them? 14 A. Both. 15 Q. Okay. And is that something 16 you still do? 17 A. Well, I would say that I work 18 closely with animal researchers as it relates 19 to translational research that I do. So -- 20 and if that's the case, then I would be 21 working with preclinical investigators to 22 inform the work that I do in terms of 23 clinical investigations. That's the point of 24 translational research, to translate findings 25 from animal models into human studies.</p>

<p>Page 26</p> <p>1 Q. So if you wanted to conduct 2 animal research on acetaminophen, you could, 3 right?</p> <p>4 A. I don't -- well, if I -- if I 5 wanted to conduct animal research with 6 acetaminophen, I wouldn't do that myself, so 7 I would probably partner with a preclinical 8 investigator.</p> <p>9 Q. Okay. And to date, you haven't 10 done that, right, Dr. Hollander?</p> <p>11 A. That's correct.</p> <p>12 Q. Okay. And if I asked you the 13 same questions about human research or 14 study -- human study, you haven't done that 15 with respect to acetaminophen either, 16 correct?</p> <p>17 MR. DOVEL: Objection. Form. 18 THE WITNESS: Well, that's 19 correct. I haven't conducted clinical 20 investigations regarding acetaminophen 21 either.</p> <p>22 QUESTIONS BY MR. MURDICA: 23 Q. Okay. If we looked at your 24 profile on Spectrum Neurosciences, would we 25 see anything at all about attention-deficit/</p>	<p>Page 28</p> <p>1 QUESTIONS BY MR. MURDICA: 2 Q. Okay. And when did 3 Dr. Hollander first come to that opinion? 4 A. I came to that opinion prior to 5 writing my amended causation expert report. 6 Q. Okay. And I just want to make 7 sure we understand each other by the way we 8 name the reports. 9 You issued an initial report in 10 this litigation, right? 11 A. Correct. 12 Q. In that initial report, you did 13 not say that acetaminophen causes -- exposure 14 during pregnancy causes autism or ASD in the 15 offspring, correct? 16 A. In my initial report I offered 17 a number of opinions, but in the initial 18 report I didn't specifically state that 19 acetaminophen causes ASD or ADHD. 20 Q. And, Doctor, that's because at 21 the time you signed your initial report, that 22 was not one of the opinions you were 23 offering, correct? 24 A. No. 25 Q. Okay. So at the time you --</p>
<p>Page 27</p> <p>1 hyperactivity disorder? 2 A. I believe you would. 3 Q. Okay. Is that one of your 4 specialties, Doctor? 5 A. That is one of my specialties. 6 Q. Okay. If somebody asked -- if 7 your colleagues, would they say 8 attention-deficit/hyperactivity disorder 9 is one of your specialties, Dr. Hollander? 10 MR. DOVEL: Objection. Form. 11 THE WITNESS: Yes, I have 12 expertise in all of the 13 neurodevelopmental disorders. 14 QUESTIONS BY MR. MURDICA: 15 Q. Okay. Dr. Hollander, is it 16 your opinion today that acetaminophen causes 17 the outcome of autism or ADHD in human beings 18 when used in utero? 19 MR. DOVEL: Objection. Form. 20 THE WITNESS: It is my opinion 21 now, today, that acetaminophen 22 exposure in utero or in pregnant women 23 can cause neurodevelopmental 24 disorders, including ASD and ADHD, in 25 offspring, in humans.</p>	<p>Page 29</p> <p>1 sorry. At the time you signed your initial 2 report, you were intending to offer the 3 opinion that acetaminophen exposure in 4 pregnancy causes ASD and ADHD in the 5 offspring? 6 A. No. At the time of my initial 7 report, I held the opinion that acetaminophen 8 causes ASD and ADHD in offspring. 9 Q. Okay. And is it your testimony 10 that it was in your initial report? That 11 that opinion was in there? 12 A. No. 13 Q. Okay. 14 A. I'm saying that I held that 15 opinion. I'm -- if you like, I can expand on 16 that. 17 Q. Well, when, Dr. Hollander, did 18 you first come to hold that opinion? 19 A. Prior to my initial report. 20 Q. Okay. Was it sometime in 2023? 21 A. Yes. 22 Q. Okay. On -- for your Spectrum 23 Neurosciences -- that's a business, right? 24 A. That's a subspecialty clinical 25 practice that specializes in</p>

<p style="text-align: right;">Page 30</p> <p>1 neurodevelopmental disorders.</p> <p>2 Q. Okay. And there's three other</p> <p>3 medical doctors that work with you as part of</p> <p>4 Spectrum Neurosciences, right?</p> <p>5 A. There are several other medical</p> <p>6 doctors as well as experts in neuropsychology</p> <p>7 and psychology and people who have expertise</p> <p>8 in other specialties that provide critical</p> <p>9 treatment for these individuals. So people</p> <p>10 who are also ancillary professionals as well.</p> <p>11 Q. Do you remember my question?</p> <p>12 A. Your question was were there</p> <p>13 three other doctors who work with me in that</p> <p>14 clinical practice?</p> <p>15 Q. Medical doctors, Dr. Hollander.</p> <p>16 There's three other medical doctors that work</p> <p>17 with you?</p> <p>18 A. I believe that there's three</p> <p>19 other medical doctors.</p> <p>20 Q. Okay. And, Dr. Hollander,</p> <p>21 which of those three other medical doctors</p> <p>22 have you told that you hold the opinion that</p> <p>23 in utero acetaminophen exposure causes autism</p> <p>24 and ADHD?</p> <p>25 A. I'm not sure that I had</p>	<p style="text-align: right;">Page 32</p> <p>1 with other individuals who have expertise in</p> <p>2 the matters at hand, and I've questioned them</p> <p>3 with regards to their opinion, and I've</p> <p>4 discussed my thoughts as well.</p> <p>5 Q. And some of those people that</p> <p>6 you've had discussions with are paid by the</p> <p>7 plaintiffs' lawyers as well, right?</p> <p>8 A. Yes. Some of those individuals</p> <p>9 are experts on behalf of the plaintiffs, yes.</p> <p>10 Q. You know that your opinion that</p> <p>11 you're offering here on causation is not</p> <p>12 to -- at this point is not widely accepted,</p> <p>13 correct?</p> <p>14 A. No.</p> <p>15 MR. DOVEL: Objection.</p> <p>16 Objection. Form.</p> <p>17 QUESTIONS BY MR. MURDICA:</p> <p>18 Q. Okay.</p> <p>19 A. I don't think I would agree</p> <p>20 with that statement.</p> <p>21 Q. Okay. Dr. Hollander, are you</p> <p>22 an obstetrician?</p> <p>23 A. No, I am not.</p> <p>24 Q. Okay. When a woman is pregnant</p> <p>25 and is asking for advice on medication during</p>
<p style="text-align: right;">Page 31</p> <p>1 specific discussions with those three</p> <p>2 individuals regarding this matter at hand.</p> <p>3 Q. Okay. You haven't told them,</p> <p>4 right?</p> <p>5 A. I don't recall whether or not I</p> <p>6 told them.</p> <p>7 Q. Have you told anyone other than</p> <p>8 the plaintiffs' lawyers?</p> <p>9 A. Yes.</p> <p>10 Q. Okay. Who have you -- let's go</p> <p>11 through who you've told.</p> <p>12 A. Well, in discussions with</p> <p>13 patients who have been considering getting</p> <p>14 pregnant, for example, or who have been</p> <p>15 pregnant, if the topic was of relevance, I</p> <p>16 may have had a discussion.</p> <p>17 Q. And that was in 2023, right,</p> <p>18 Dr. Hollander?</p> <p>19 A. That's correct.</p> <p>20 Q. Okay. Outside of patients that</p> <p>21 you may or may not have told that you believe</p> <p>22 that acetaminophen causes autism and ADHD,</p> <p>23 have you told any medical professionals that</p> <p>24 you believe that?</p> <p>25 A. Well, I have had discussions</p>	<p style="text-align: right;">Page 33</p> <p>1 pregnancy, would the first stop be an</p> <p>2 obstetrician?</p> <p>3 MR. DOVEL: Objection.</p> <p>4 QUESTIONS BY MR. MURDICA:</p> <p>5 Q. To ask for advice?</p> <p>6 MR. DOVEL: Form. Objection.</p> <p>7 Form.</p> <p>8 THE WITNESS: You know, if a</p> <p>9 woman is pregnant or considering being</p> <p>10 pregnant, then they might seek</p> <p>11 information from different sources.</p> <p>12 So it might be an obstetrician. It</p> <p>13 might be someone who deals with</p> <p>14 high-risk pregnancies because these</p> <p>15 issues may be particularly of interest</p> <p>16 in people who specialize in high-risk</p> <p>17 pregnancies. It might be someone who</p> <p>18 specializes in maternal-fetal</p> <p>19 medicine. So -- and also someone who</p> <p>20 has expertise who can discuss the</p> <p>21 risks and benefits of different kinds</p> <p>22 of medications for both the mother and</p> <p>23 for the offspring.</p> <p>24 QUESTIONS BY MR. MURDICA:</p> <p>25 Q. Okay. Dr. Hollander, are you</p>

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1 an MFM? Are you an expert in maternal-fetal
2 medicine?

3 A. Well, I see many women who have
4 issues around medication usage during
5 pregnancy, and I can offer advice.

6 I also sometimes refer patients
7 to individuals, for example, within my
8 practice or outside of the practice who also
9 have expertise in maternal-fetal medicine.

10 So I would want to seek and get
11 consultation from individuals with a range of
12 experience and knowledge and background.

13 Q. Dr. Hollander, are you a member
14 of the Society of Maternal-Fetal Medicine?

15 A. No.

16 Q. Okay. Are you a member of the
17 American College of Obstetricians and
18 Gynecologists?

19 A. No.

20 Q. Do you recognize ACOG as the
21 body that has expertise in obstetrics and
22 gynecology?

23 A. Yes.

24 Q. Everyone that's a member of
25 ACOG is board certified in obstetrics and

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1 gynecology, correct?

2 A. I would think so, but I'm not
3 certain about that.

4 Q. Okay. Have you seen what the
5 American College of Obstetricians and
6 Gynecologists have said about the
7 relationship between acetaminophen and the
8 outcomes of autism and ADHD?

9 A. I have had the opportunity to
10 review different consensus statements issued
11 by different bodies that relate to this
12 matter.

13 Q. Right.

14 A. And I'm aware that there's
15 different consensus statements and opinions
16 that have been offered on this matter.

17 Q. The 60,000 board certified
18 obstetricians and gynecologists in the United
19 States disagree with your opinions here, and
20 you know that, right?

21 MR. DOVEL: Objection. Form.

22 THE WITNESS: Well, again, I
23 would say that there are different
24 bodies that have offered different
25 opinions with regards to this matter.

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1 QUESTIONS BY MR. MURDICA:

2 Q. Does ACOG agree with you,
3 Dr. Hollander?

4 MR. DOVEL: Objection. Form.

5 THE WITNESS: Not at this time.

6 QUESTIONS BY MR. MURDICA:

7 Q. Okay. And that was my original
8 question, Dr. Hollander.

9 A. Yes.

10 Q. At this time --

11 A. Right.

12 Q. -- your opinion that
13 acetaminophen causes ASD and ADHD during
14 pregnancy is controversial, correct?

15 MR. DOVEL: Objection. Form.

16 THE WITNESS: Well, I would say
17 that there are different opinions, and
18 I do think that that is consistent
19 with the history of medicine.

20 As, you know, additional
21 evidence appears and as different
22 analyses appear in the literature,
23 that influences recommendations and
24 treatment practice. And those
25 recommendations evolve over time, yes.

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1 QUESTIONS BY MR. MURDICA:

2 Q. Right.

3 For example, back in the early
4 2000s, you were offering opinions regarding
5 the MMR and thimerosal issues, correct?

6 A. No.

7 Q. Okay. I didn't mean offering
8 opinions for plaintiffs' lawyers. I meant
9 you were tracking that and talking about it
10 in your regular work, correct?

11 A. No. I was not offering
12 opinions with regards to that matter.

13 Q. Okay. You know that initially
14 vaccines were thought to be related to the
15 outcome of autism, right?

16 A. I understand that that's an
17 area of controversy. It's not something --
18 that's not an opinion that I've held.

19 Q. Okay. Well, let's ask you
20 today, Dr. Hollander.

21 Does the MMR vaccine cause
22 autism?

23 A. As of today, no, I don't
24 believe that the MMR vaccine causes autism.

25 Q. At one point there were

<p style="text-align: right;">Page 38</p> <p>1 reputable doctors who were opining that it 2 did, right?</p> <p>3 MR. DOVEL: Objection. Form.</p> <p>4 THE WITNESS: Well, I've never 5 held that opinion. At one point there 6 were some doctors who held that 7 opinion, but I want to make it clear 8 that I've never held that opinion.</p> <p>9 QUESTIONS BY MR. MURDICA:</p> <p>10 Q. And it -- in your view, it 11 turned out that those doctors that held the 12 opinion that the MMR vaccine causes autism 13 ended up being wrong, right?</p> <p>14 MR. DOVEL: Objection. Form.</p> <p>15 THE WITNESS: I believe that's 16 true, yes.</p> <p>17 QUESTIONS BY MR. MURDICA:</p> <p>18 Q. All right. And right now, the 19 opinion you're offering here, Dr. Hollander, 20 is not generally accepted yet, right?</p> <p>21 MR. DOVEL: Objection. Form.</p> <p>22 THE WITNESS: No, I disagree. 23 So I think that the -- as the evidence 24 is accumulating, I think that more and 25 more individuals and bodies are</p>	<p style="text-align: right;">Page 40</p> <p>1 and they've suggested that in order to 2 make a determination, that it's 3 important to be able to study the 4 animal model literature in order to be 5 able to come up with an opinion. And, 6 therefore, they've recommended that 7 animal studies should be conducted and 8 should be funded.</p> <p>9 QUESTIONS BY MR. MURDICA:</p> <p>10 Q. Okay. And, Dr. Hollander, you 11 may not remember my question, but I'm asking 12 about as of August 2023, the FDA has had 13 numerous opportunities to weigh in on whether 14 the labeling of acetaminophen should be 15 changed to add a risk of ASD or ADHD, 16 correct?</p> <p>17 MR. DOVEL: Objection. Form.</p> <p>18 THE WITNESS: That's correct, 19 that the FDA has considered the matter 20 with regards to labeling changes. 21 The FDA has issued labeling 22 changes as it relates to 23 acetaminophen. 24 So, for example, with 25 intravenous acetaminophen and/or if</p>
<p style="text-align: right;">Page 39</p> <p>1 studying this in more detail, and I 2 believe that their opinions are 3 changing, yes.</p> <p>4 QUESTIONS BY MR. MURDICA:</p> <p>5 Q. Okay. As of today --</p> <p>6 A. Yes.</p> <p>7 Q. -- right? We're sitting here 8 in August 2023 --</p> <p>9 A. That's right.</p> <p>10 Q. -- the American College of 11 Obstetricians and Gynecologists disagrees 12 with you as of today, correct?</p> <p>13 A. As of today, correct.</p> <p>14 Q. Okay. The Society for 15 Maternal-Fetal Medicine, as of today, 16 disagrees with you, correct?</p> <p>17 MR. DOVEL: Objection. Form.</p> <p>18 THE WITNESS: I believe so.</p> <p>19 QUESTIONS BY MR. MURDICA:</p> <p>20 Q. Okay. FDA, as of today, 21 disagrees with you, correct?</p> <p>22 MR. DOVEL: Objection. Form.</p> <p>23 THE WITNESS: No, I don't agree 24 with that. I think that the FDA has 25 evaluated the epidemiology evidence,</p>	<p style="text-align: right;">Page 41</p> <p>1 acetaminophen is combined with 2 tramadol, yes, they've changed the 3 labeling as a result of incorporating 4 both the animal data and the human 5 data, yes.</p> <p>6 QUESTIONS BY MR. MURDICA:</p> <p>7 Q. Do you remember my question, 8 Dr. Hollander?</p> <p>9 MR. DOVEL: Objection. Form.</p> <p>10 THE WITNESS: Perhaps you can 11 repeat your question if you're not 12 satisfied with my response.</p> <p>13 QUESTIONS BY MR. MURDICA:</p> <p>14 Q. Sure.</p> <p>15 Dr. Hollander, are you aware 16 that many times in the last five to seven 17 years, FDA has been asked whether 18 acetaminophen labeling should be updated in 19 the pregnancy section to include a warning 20 about ADHD?</p> <p>21 Are you aware of that?</p> <p>22 A. Yes.</p> <p>23 MR. DOVEL: Objection. Form.</p> <p>24 QUESTIONS BY MR. MURDICA:</p> <p>25 Q. Are you aware of a statement</p>

<p style="text-align: right;">Page 42</p> <p>1 that FDA made in 2016 that there wasn't 2 enough evidence to do so?</p> <p>3 MR. DOVEL: Objection. Form.</p> <p>4 QUESTIONS BY MR. MURDICA:</p> <p>5 Q. Have you ever seen that?</p> <p>6 A. I'm aware. However, I'm also 7 aware of the statement that the FDA has made 8 that in order to make a definitive 9 conclusion, that they would want to look at 10 all of the available data, and that in order 11 to answer the question, they would need to 12 review the animal data.</p> <p>13 Q. Okay. And what --</p> <p>14 A. And in addition to that, that 15 that work should continue to be done and be 16 funded.</p> <p>17 Q. What statement was that, 18 Dr. Hollander? When was that?</p> <p>19 A. That was a response to some of 20 their reviews with regard to this matter.</p> <p>21 Q. Okay. Was that a public 22 statement?</p> <p>23 A. It was a statement that they 24 issued, yes.</p> <p>25 Q. Okay. When did they issue that</p>	<p style="text-align: right;">Page 44</p> <p>1 A. I'll have to take a look at the 2 statements, actually, to determine which one 3 it is.</p> <p>4 Q. Okay. But it's your belief 5 that FDA made a -- made a public statement to 6 the effect of what you just testified?</p> <p>7 A. Yeah. It's my belief that 8 they've said that in order to answer the 9 question, that they need to be able to 10 incorporate the animal model data in order to 11 make a decision.</p> <p>12 Q. Okay. So, Dr. Hollander, you 13 didn't -- you didn't see anything in your 14 review where FDA said that further animal 15 study is unlikely to provide better 16 information?</p> <p>17 A. I don't agree with that 18 statement, no.</p> <p>19 Q. Did you see that? Did you see 20 that FDA said that?</p> <p>21 A. Perhaps you can show me that 22 statement, and then I can respond to that.</p> <p>23 Q. Sure.</p> <p>24 I'm asking, sitting here today, 25 do you remember ever seeing that?</p>
<p style="text-align: right;">Page 43</p> <p>1 statement, Dr. Hollander?</p> <p>2 A. Maybe I can look at my 3 materials considered, and then I can go take 4 a look and see when that occurred.</p> <p>5 Q. Sure. You can take a couple 6 minutes to do that if you're able to find it.</p> <p>7 A. Okay. Well, so I see that 8 there are three relevant documents here. 9 One, the -- well, so I'm looking at the 10 package insert statements that they've issued 11 with regards to Ofirmev and also -- which 12 was -- and then another one with regards to 13 analgesics and antipyretics.</p> <p>14 And then I have their 15 regulatory guidelines in 20 -- in January 31, 16 2023.</p> <p>17 And then I also see their 18 background and overview statement in 2009.</p> <p>19 Q. Okay. Dr. Hollander, which of 20 those allegedly contains the statement that 21 you just testified to?</p> <p>22 A. That -- about the need to look 23 at the data, including animal models and to 24 conduct more animal models?</p> <p>25 Q. Sure.</p>	<p style="text-align: right;">Page 45</p> <p>1 MR. DOVEL: Objection. Form.</p> <p>2 THE WITNESS: I don't -- I 3 don't remember reading a statement 4 where FDA said that animal data would 5 not inform a decision with regards to 6 this matter. No, I don't remember 7 that.</p> <p>8 QUESTIONS BY MR. MURDICA:</p> <p>9 Q. Okay. Have you seen FDA's 10 statements this year that it continues to 11 review information regarding acetaminophen 12 and ADHD and ASD outcomes in pregnancy in 13 response to questions of whether the labeling 14 should be changed?</p> <p>15 A. Yes. It's my understanding 16 that FDA is continuing to consider the matter 17 and that, you know, as additional information 18 becomes available, both with regards to 19 epidemiology and with regard to the animal 20 models, then FDA may offer additional 21 opinions with regards to labeling changes.</p> <p>22 Q. All right. And do you have any 23 doubt that FDA is actually reviewing the 24 information as it comes out?</p> <p>25 A. I don't have any doubt that FDA</p>

<p style="text-align: right;">Page 46</p> <p>1 would be continuing to review the 2 information. And the information continues 3 to come out, so I know that it's on their 4 radar, and I would expect that they would 5 continue to review information as it becomes 6 available. 7 Q. Right. 8 And you have a high opinion of 9 FDA's ability to review information regarding 10 drug safety, right? 11 MR. DOVEL: Objection. Form. 12 THE WITNESS: Well, so FDA and 13 pharmacovigilance advisory groups with 14 regards to FDA are responsible for 15 evaluating information with regards to 16 safety and efficacy as it continues to 17 come out. 18 However -- and in -- this is 19 the history of multiple medications 20 with regards to labeling. As 21 additional information comes out, FDA 22 revises the labeling accordingly. 23 Sometimes there's a lag time 24 between when the information comes out 25 and when the labeling changes occur,</p>	<p style="text-align: right;">Page 48</p> <p>1 under the same regulatory 2 considerations from the FDA once it 3 became an over-the-counter product. 4 And at the time that it went over the 5 counter, the practices were very, very 6 different than they are currently now. 7 But I can say that with recent 8 prescription compounds that include 9 acetaminophen, yes, the label has 10 changed to reflect a more accurate 11 review of the literature with regards 12 to safety and efficacy, yes. 13 QUESTIONS BY MR. MURDICA: 14 Q. Are you done, Dr. Hollander? 15 A. Yes. 16 Q. Do you think you answered my 17 question? 18 A. I believe so. 19 MR. MURDICA: Okay. Would you 20 read back my last question, please, if 21 you can find it? 22 (Court Reporter read back 23 question.) 24 MR. DOVEL: Did you want to 25 have that question reposed? Or are</p>
<p style="text-align: right;">Page 47</p> <p>1 but the FDA does incorporate new 2 information and does issue labeling 3 changes to reflect the state of the 4 art with regard to the safety and 5 efficacy. Absolutely. 6 QUESTIONS BY MR. MURDICA: 7 Q. And, Dr. Hollander, as we sit 8 here today in August 2023, FDA has not 9 suggested that acetaminophen labeling should 10 say that ASD and ADHD are an increased risk 11 when used during pregnancy, correct? 12 MR. DOVEL: Objection. Form. 13 THE WITNESS: Well, the FDA has 14 actually changed the package insert or 15 the labeling with regards to 16 acetaminophen as the new information 17 has come out. And so as I've 18 mentioned, they have incorporated 19 labeling changes for the compound. 20 One of the issues here is that 21 this is a compound that was developed 22 in the 1890s. It was originally 23 approved by the FDA early 1950s. 24 In the later 1950s, it went 25 over the counter, so it was no longer</p>	<p style="text-align: right;">Page 49</p> <p>1 you just having it read back? 2 MR. MURDICA: No, I'm having it 3 reposed. 4 MR. DOVEL: Objection. Form. 5 QUESTIONS BY MR. MURDICA: 6 Q. Can you answer that question, 7 Dr. Hollander? 8 A. Yeah. Perhaps you could 9 restate that question, because I believe that 10 there were a few different components that 11 were included within the same question. 12 MR. MURDICA: Okay. Would you 13 ask it again, please? 14 (Court Reporter read back 15 question.) 16 MR. DOVEL: Objection. Form. 17 THE WITNESS: Well, my answer 18 would be the same, actually. So that 19 the product labeling more recently for 20 prescription forms of acetaminophen 21 have reflected a change in the -- in 22 the risk versus the benefit or the 23 safety. Specifically now, they're 24 included as a Category C. 25</p>

<p style="text-align: right;">Page 50</p> <p>1 QUESTIONS BY MR. MURDICA:</p> <p>2 Q. Dr. Hollander, are you unable</p> <p>3 to answer the question?</p> <p>4 A. The --</p> <p>5 MR. DOVEL: Objection. Form.</p> <p>6 THE WITNESS: The last question</p> <p>7 that I just heard, I was answering</p> <p>8 that question, so --</p> <p>9 QUESTIONS BY MR. MURDICA:</p> <p>10 Q. Does the acetaminophen labeling</p> <p>11 today contain anything about autism or ADHD?</p> <p>12 MR. DOVEL: Objection. Form.</p> <p>13 THE WITNESS: Well, no, the</p> <p>14 answer is the labeling today does not</p> <p>15 include anything --</p> <p>16 QUESTIONS BY MR. MURDICA:</p> <p>17 Q. Okay.</p> <p>18 A. -- with regards to ASD and</p> <p>19 ADHD.</p> <p>20 However, I believe that the</p> <p>21 question that the court reporter just read to</p> <p>22 me didn't say -- state that, actually.</p> <p>23 Q. Okay. We're going to go back</p> <p>24 and ask it again, Dr. Hollander, and if you</p> <p>25 can't --</p>	<p style="text-align: right;">Page 52</p> <p>1 MR. MURDICA: Sure.</p> <p>2 MR. DOVEL: The witness has</p> <p>3 been answering directly. I've been</p> <p>4 posing objections.</p> <p>5 I can see the problem with your</p> <p>6 question. You just can't see the</p> <p>7 problem with your question. His</p> <p>8 answers are very accurate.</p> <p>9 MR. MURDICA: Wonderful. Thank</p> <p>10 you. Perhaps on the break you can</p> <p>11 give me some free advice. But thank</p> <p>12 you.</p> <p>13 MR. DOVEL: I don't give free</p> <p>14 advice. I'm going to charge you for</p> <p>15 it.</p> <p>16 MR. MURDICA: All right. It</p> <p>17 ain't worth it.</p> <p>18 All right. If you could ask</p> <p>19 the question that the doctor has been</p> <p>20 unable to answer one more time, I'd</p> <p>21 appreciate it.</p> <p>22 (Court Reporter read back</p> <p>23 question.)</p> <p>24 MR. DOVEL: Objection. Form.</p> <p>25 THE WITNESS: Correct.</p>
<p style="text-align: right;">Page 51</p> <p>1 A. Okay.</p> <p>2 Q. -- answer it, we're going to</p> <p>3 take a break to decide to what to do with the</p> <p>4 rest of the deposition. Because I'm not</p> <p>5 going to spend my day having you give</p> <p>6 nonresponsive answers, because there's better</p> <p>7 things we can do with our time. So we'll try</p> <p>8 it one more time.</p> <p>9 MR. DOVEL: The witness has</p> <p>10 been extremely responsive.</p> <p>11 MR. MURDICA: Yeah, that's just</p> <p>12 not -- that's not true.</p> <p>13 MR. DOVEL: Please don't</p> <p>14 interrupt me.</p> <p>15 MR. MURDICA: That's not true.</p> <p>16 MR. DOVEL: We'll get through</p> <p>17 today better if you don't interrupt</p> <p>18 me.</p> <p>19 MR. MURDICA: Okay.</p> <p>20 MR. DOVEL: Our court reporter</p> <p>21 is excellent, but she can only write</p> <p>22 down one person at a time.</p> <p>23 MR. MURDICA: I agree.</p> <p>24 MR. DOVEL: So let me go ahead</p> <p>25 and finish my statement.</p>	<p style="text-align: right;">Page 53</p> <p>1 QUESTIONS BY MR. MURDICA:</p> <p>2 Q. Okay. Dr. Hollander, are you</p> <p>3 aware of any medical organizations that as of</p> <p>4 today, in August 2023, agree with your</p> <p>5 causation opinion here?</p> <p>6 A. Yes.</p> <p>7 Q. Okay. And what medical</p> <p>8 organization is that?</p> <p>9 A. Well, the pharmacovigilance</p> <p>10 committee that advises the European</p> <p>11 medical -- EMA has offered that opinion. So</p> <p>12 that is a medical and regulatory advisory</p> <p>13 group.</p> <p>14 Q. Okay. Let's take this one step</p> <p>15 at a time then.</p> <p>16 In the United States, is there</p> <p>17 any medical organization, to your knowledge,</p> <p>18 that agrees with the causation opinion you're</p> <p>19 offering here that acetaminophen causes</p> <p>20 autism and ADHD?</p> <p>21 MR. DOVEL: Objection. Form.</p> <p>22 THE WITNESS: Well, yes.</p> <p>23 QUESTIONS BY MR. MURDICA:</p> <p>24 Q. Okay. Which medical</p> <p>25 organization in the United States?</p>

<p style="text-align: right;">Page 54</p> <p>1 A. The Bauer consensus statement</p> <p>2 that was published represented a large number</p> <p>3 of medical experts across different</p> <p>4 scientific disciplines that explicitly</p> <p>5 reviewed the literature in 29 different</p> <p>6 studies and then, based on that, offered</p> <p>7 specific opinions with regards to safety and</p> <p>8 efficacy and also with regards to, you know,</p> <p>9 regulatory guidelines and package insert.</p> <p>10 Q. Okay. Dr. Hollander, is the --</p> <p>11 are the 91 people who signed the consensus</p> <p>12 statement, are they their own medical</p> <p>13 society?</p> <p>14 MR. DOVEL: Objection. Form.</p> <p>15 THE WITNESS: I'm not sure</p> <p>16 whether they're incorporated as a</p> <p>17 medical society. They do represent</p> <p>18 individuals from a broad range of</p> <p>19 different medical societies who have</p> <p>20 scientific expertise and are able to</p> <p>21 review the literature and offer</p> <p>22 opinions.</p> <p>23 QUESTIONS BY MR. MURDICA:</p> <p>24 Q. For example, two of the 91 are</p> <p>25 members of ACOG and disagree with the 60,000</p>	<p style="text-align: right;">Page 56</p> <p>1 at hand.</p> <p>2 Q. Okay. Is Briggs a medical</p> <p>3 organization?</p> <p>4 A. No.</p> <p>5 Q. Okay.</p> <p>6 A. Briggs is a well-regarded,</p> <p>7 validated textbook that informs individuals</p> <p>8 that work with pregnant mothers and doctors</p> <p>9 who specialize in that, you know, what are</p> <p>10 appropriate practices with regards to</p> <p>11 different medicines.</p> <p>12 Q. Okay. And, Dr. Hollander, back</p> <p>13 to my question --</p> <p>14 A. Yes.</p> <p>15 Q. -- which is, United States</p> <p>16 medical organizations or societies that share</p> <p>17 your opinion that acetaminophen causes autism</p> <p>18 and ADHD.</p> <p>19 The answer is, you can't think</p> <p>20 of one, correct?</p> <p>21 A. I can't recall one at this</p> <p>22 time.</p> <p>23 Q. Okay.</p> <p>24 A. I can look into that and get</p> <p>25 back to you.</p>
<p style="text-align: right;">Page 55</p> <p>1 that have said that -- that have come out</p> <p>2 that we agreed earlier do not agree with the</p> <p>3 opinion, correct?</p> <p>4 MR. DOVEL: Objection. Form.</p> <p>5 THE WITNESS: Well, I do agree</p> <p>6 that this is a controversial area. I</p> <p>7 do agree that different organizations</p> <p>8 have offered different opinions. And</p> <p>9 I do agree that opinions do change</p> <p>10 over time as more evidence</p> <p>11 accumulates.</p> <p>12 QUESTIONS BY MR. MURDICA:</p> <p>13 Q. Okay. Dr. Hollander, what</p> <p>14 United States medical organizations have</p> <p>15 offered the opinion that acetaminophen causes</p> <p>16 autism and ADHD in offspring?</p> <p>17 A. I'm not sure that I could</p> <p>18 recall a specific medical organization in the</p> <p>19 United States.</p> <p>20 I do know, for example, that</p> <p>21 textbooks such as the Briggs textbook, which</p> <p>22 talks about fetal -- which is the expert</p> <p>23 reference with regards to fetal medicine and</p> <p>24 exposure, have modified the guidelines and</p> <p>25 offered opinions with regards to this matter</p>	<p style="text-align: right;">Page 57</p> <p>1 Q. Okay. We'll leave a -- we'll</p> <p>2 leave a blank in the transcript. There are</p> <p>3 none, but we're going to leave a blank in the</p> <p>4 transcript --</p> <p>5 A. Okay.</p> <p>6 Q. -- so you can go back and</p> <p>7 determine that there are none, and then you</p> <p>8 can fill it in.</p> <p>9 Okay?</p> <p>10 MR. DOVEL: No, he's not going</p> <p>11 to be filling in any blanks.</p> <p>12 MR. MURDICA: Well, he asked</p> <p>13 for it, Counsel.</p> <p>14 MR. DOVEL: No, he didn't ask</p> <p>15 for a blank.</p> <p>16 MR. MURDICA: He said he would</p> <p>17 get back to us. We'll put a blank in</p> <p>18 the transcript that will remain blank</p> <p>19 because there are none.</p> <p>20 QUESTIONS BY MR. MURDICA:</p> <p>21 Q. All right. Next question. You</p> <p>22 mentioned --</p> <p>23 A. Well, maybe just to complete my</p> <p>24 thought then.</p> <p>25 So I haven't -- I haven't</p>

<p style="text-align: right;">Page 58</p> <p>1 really considered the matter, and I haven't 2 searched all of the different medical 3 organizations in the United States and 4 haven't determined whether they've offered an 5 opinion on this matter. So I can't really 6 say one way or another because I haven't 7 really considered that question. 8 Q. Okay. Dr. Hollander, sitting 9 here today, you're not aware of any United 10 States medical organization or society that 11 agrees with you that acetaminophen causes 12 autism and ADHD in offspring? 13 A. Well, again, I would repeat 14 that I haven't considered the matter, and I 15 haven't searched each of the recommendations 16 for each of the different medical 17 organizations in the United States. 18 Q. Fair. 19 But you can't -- I'm sorry, I 20 didn't mean to cut you off. Go ahead. 21 A. And so I -- to my knowledge at 22 this time, I can't recall one, although I 23 haven't considered that matter. And so it's 24 hard for me to really respond. 25 Q. Okay. Dr. Hollander, in</p>	<p style="text-align: right;">Page 60</p> <p>1 autism spectrum disorders, and there's about 2 a paragraph that discusses the matter and in 3 particular highlights one of the 4 meta-analysis, the Masarwa meta-analysis, 5 that did suggest an increased odds ratio 6 between exposure, acetaminophen, and outcome, 7 ASD, in that context. 8 Q. I want you to listen carefully 9 to my question. 10 If we looked at your textbooks, 11 Dr. Hollander, any of the chapters, any of 12 the pages, would any of them say that 13 acetaminophen causes ADHD? 14 A. Well, one of the textbooks is 15 on a different area, so it wouldn't be talked 16 about in that text. 17 But one of the textbooks does 18 relate to autism. If we review the paragraph 19 in that textbook that reviews the literature 20 as of -- so one issue there is that the 21 textbook came out in 2022. Probably was 22 originally written around 2019. 23 In that particular review, 24 there is one meta-analysis that is cited that 25 raises the issue but doesn't come up with a</p>
<p style="text-align: right;">Page 59</p> <p>1 response to a question a moment ago you 2 mentioned a textbook. 3 Do you remember that? 4 A. Yes. 5 Q. Okay. And Dr. Hollander has a 6 textbook as well, right? 7 A. That's correct. 8 Q. Okay. 9 A. Well, no, that's not correct 10 because I have more than one textbook. 11 Q. Okay. That's a fair point. 12 How many textbooks do you have 13 that are currently in publication, Doctor? 14 A. Well, I have two popular 15 textbooks that have had multiple editions. 16 Q. Okay. And those textbooks 17 contain chapters on, for example, causes of 18 autism, right? 19 A. Yes. 20 Q. Okay. And if we looked, would 21 any of your textbooks, any of your chapters, 22 any of the pages in your textbooks today, say 23 that acetaminophen causes ADHD? 24 A. Well, yes, I believe that the 25 matter was considered in the textbook of</p>	<p style="text-align: right;">Page 61</p> <p>1 definitive conclusion. It suggests that 2 future work needs to be done and that one 3 might consider the issue of confounders as 4 well. 5 Nevertheless, they do talk 6 about this issue. They do cite one of the 7 meta-analyses. The meta-analysis does 8 suggest the increased risk between exposure 9 and outcome, but that -- in that particular 10 paragraph, there's no definitive opinion with 11 regards to causation, and they suggest that 12 the matter needs to continue to be studied. 13 Q. Okay. Dr. Hollander, I take it 14 if you're citing to some particular 15 paragraph, you looked at this recently; is 16 that right? 17 A. Yes, I have. 18 Q. In the past 24 hours? 19 A. No. 20 Q. Okay. Dr. Hollander, does the 21 textbook -- so I asked a question about ADHD. 22 You're talking about autism. So I'll ask a 23 question about autism. 24 Does your textbook say that 25 acetaminophen causes autism?</p>

<p style="text-align: right;">Page 62</p> <p>1 A. Okay. Then -- so -- and I'm</p> <p>2 sorry, I thought you had been asking about</p> <p>3 autism, not ADHD.</p> <p>4 I don't believe there are</p> <p>5 statements with regards to -- or that there's</p> <p>6 any review, actually, with regards to</p> <p>7 acetaminophen and ADHD mentioned in the</p> <p>8 textbook. So the textbooks deal with</p> <p>9 different issues.</p> <p>10 With regard to autism, yes.</p> <p>11 Q. It says acet -- okay. I just</p> <p>12 want to be clear.</p> <p>13 Dr. Hollander's textbook</p> <p>14 says -- published in 2022, right?</p> <p>15 A. Well, so it was published in</p> <p>16 2022, the material in it.</p> <p>17 So one issue with textbooks is</p> <p>18 that sometimes -- textbooks are a general</p> <p>19 overview of a particular area. It takes a</p> <p>20 long, long time for those textbooks to be</p> <p>21 prepared and integrated. Then you need to</p> <p>22 have paper shipped from Canada into the</p> <p>23 United States. There can be long delays in</p> <p>24 terms of when the material is prepared, let's</p> <p>25 say, 2019, and when the textbook comes out,</p>	<p style="text-align: right;">Page 64</p> <p>1 A. Yes.</p> <p>2 Q. -- whenever you signed off on</p> <p>3 what was in it, it does not say the words,</p> <p>4 "acetaminophen causes autism in exposed</p> <p>5 babies," correct?</p> <p>6 A. I'm not sure it says those</p> <p>7 particular words.</p> <p>8 What I can say is, again, you</p> <p>9 know, there's about a -- one paragraph. It's</p> <p>10 a selective review with one meta-analysis.</p> <p>11 So it's not a comprehensive, deep dive in</p> <p>12 terms of the available literature or even the</p> <p>13 available meta-analyses that were -- knew at</p> <p>14 that time.</p> <p>15 One thing that I would also say</p> <p>16 is that -- so I was overall editor for the</p> <p>17 textbook, but I also had two coeditors. The</p> <p>18 particular -- so what we did is we divided up</p> <p>19 the textbook into different groupings. One</p> <p>20 of the other editors was the responsible</p> <p>21 editor for that particular chapter, so I</p> <p>22 didn't serve as the primary editor on that</p> <p>23 chapter.</p> <p>24 I did serve as the overall</p> <p>25 editor for the textbook.</p>
<p style="text-align: right;">Page 63</p> <p>1 2022. So sometimes textbooks may not have</p> <p>2 the most recent information. And as a -- as</p> <p>3 an overview, they may not have studied all of</p> <p>4 the information at hand or included all of</p> <p>5 the available studies or all of the available</p> <p>6 meta-analyses at that time.</p> <p>7 But nevertheless, it is</p> <p>8 significant that in that textbook, yes, they</p> <p>9 did discuss the issue with regards to</p> <p>10 exposure and outcome, and they did cite an</p> <p>11 important meta-analytic study that reviews</p> <p>12 the material, but that they make some general</p> <p>13 statements, well, clearly, you need to</p> <p>14 consider confounders when you're looking at</p> <p>15 exposure and outcome and more work should be</p> <p>16 done.</p> <p>17 Q. And, Dr. Hollander, that</p> <p>18 meta-analysis you're talking about is the</p> <p>19 2008 {sic} publication Masarwa; is that</p> <p>20 correct?</p> <p>21 A. No, I believe that's 2019.</p> <p>22 Q. 2019. Okay.</p> <p>23 Dr. Hollander, my question was,</p> <p>24 when we open your 2022 textbook, whenever it</p> <p>25 was created --</p>	<p style="text-align: right;">Page 65</p> <p>1 Q. Dr. Hollander, did you review</p> <p>2 the content of the textbook before you put</p> <p>3 your name on it?</p> <p>4 A. Yes, I -- well, I not only</p> <p>5 reviewed all of the material, but that I also</p> <p>6 assigned specific chapters to different</p> <p>7 editors for them to do specific review as</p> <p>8 well for certain areas.</p> <p>9 Q. Right.</p> <p>10 And if you had any question,</p> <p>11 concern or disagreement with anything in the</p> <p>12 textbook with your name on it, you could have</p> <p>13 called, written, asked questions about it to</p> <p>14 make sure that it reflected your thoughts,</p> <p>15 what you thought was appropriate, correct?</p> <p>16 A. Well, I would say that at that</p> <p>17 time I hadn't reviewed the literature, I</p> <p>18 hadn't weighted the evidence, and I hadn't</p> <p>19 formed an opinion with regards to this</p> <p>20 matter.</p> <p>21 Q. Okay. So in 2019 -- well,</p> <p>22 you're saying this was -- the 2022 textbook,</p> <p>23 your testimony is that that's content as of</p> <p>24 2019, right?</p> <p>25 A. Yeah. Most of the chapters</p>

<p style="text-align: right;">Page 66</p> <p>1 were being submitted around 2019, and then it</p> <p>2 eventually got published at around 2022.</p> <p>3 Q. So in 2019, the 2019 content,</p> <p>4 when we look at what Dr. Hollander said,</p> <p>5 we're not going to find Dr. Hollander</p> <p>6 saying -- or his chapter saying that</p> <p>7 acetaminophen causes ADHD or autism, correct?</p> <p>8 A. Well, again, what I would say</p> <p>9 is that in the chapter, this issue is raised</p> <p>10 that a particular meta-analysis, the Masarwa</p> <p>11 meta-analysis, which is a -- is a pooling of</p> <p>12 data from multiple different studies to look</p> <p>13 at things like odds ratio in a large sample</p> <p>14 size, raised the issue.</p> <p>15 The authors who did a -- I</p> <p>16 would say a selective review, not a</p> <p>17 comprehensive review, said that what -- when</p> <p>18 you're discussing issues about exposure and</p> <p>19 outcome, of course you need to consider</p> <p>20 confounders as well, and additional work</p> <p>21 needs to be done.</p> <p>22 So there was not a statement,</p> <p>23 that's correct, in the chapter at that time</p> <p>24 that said APAP, or acetaminophen, causes ASD.</p> <p>25 There is a statement that says</p>	<p style="text-align: right;">Page 68</p> <p>1 while. We've sold a certain number of books.</p> <p>2 We think it would be a good -- appropriate</p> <p>3 time to publish a new edition.</p> <p>4 So, for example, I have a</p> <p>5 textbook on anxiety, obsessive compulsive and</p> <p>6 posttraumatic stress disorders where we've</p> <p>7 been through this process, and three</p> <p>8 different times they've contacted me and</p> <p>9 asked for an additional edition.</p> <p>10 And that did happen in the</p> <p>11 autism textbook as well, but I have no idea</p> <p>12 when that might happen again with regard -- I</p> <p>13 mean, the autism textbook is still relatively</p> <p>14 new because it was only published in 2022.</p> <p>15 Q. Okay. So as of today, you're</p> <p>16 not working on a new edition of the 2022</p> <p>17 Hollander textbook?</p> <p>18 A. No.</p> <p>19 Q. Okay. Have you attempted to</p> <p>20 publish this opinion that you now hold, that</p> <p>21 acetaminophen causes autism and ADHD,</p> <p>22 anywhere?</p> <p>23 A. No.</p> <p>24 Q. Are you going to?</p> <p>25 A. I don't have any immediate</p>
<p style="text-align: right;">Page 67</p> <p>1 there is literature and there are</p> <p>2 meta-analyses that suggest that that is a</p> <p>3 possibility and that additional -- additional</p> <p>4 literature should be reviewed and additional</p> <p>5 work should be done to come up with a</p> <p>6 specific causation opinion.</p> <p>7 Q. And, Dr. Hollander, that</p> <p>8 Masarwa meta-analysis is one of the studies</p> <p>9 that you say is most important to your</p> <p>10 opinion that acetaminophen causes autism and</p> <p>11 ADHD in offspring, correct?</p> <p>12 MR. DOVEL: Objection. Form.</p> <p>13 THE WITNESS: Well, that</p> <p>14 particular meta-analysis is an</p> <p>15 important study. It is one of several</p> <p>16 meta-analyses. And all of those</p> <p>17 meta-analyses show a positive</p> <p>18 association between the exposure and</p> <p>19 the outcome.</p> <p>20 QUESTIONS BY MR. MURDICA:</p> <p>21 Q. Do you have, Dr. Hollander, any</p> <p>22 textbook revisions underway right now?</p> <p>23 A. No. Usually that happens when</p> <p>24 the publishers, you know, contact the editors</p> <p>25 and they say, well, this has been out for a</p>	<p style="text-align: right;">Page 69</p> <p>1 plans to do that. It's possible that at some</p> <p>2 future time I might be asked to contribute to</p> <p>3 a consensus statement, but I have no thoughts</p> <p>4 or plans to do that at this point.</p> <p>5 Q. Okay. And back to your</p> <p>6 compensation here.</p> <p>7 You're being paid an hourly</p> <p>8 rate, right?</p> <p>9 A. That's correct.</p> <p>10 Q. Okay. And what's the hourly</p> <p>11 rate?</p> <p>12 A. My hourly rate is the same as</p> <p>13 my hourly rate in my clinical practice, which</p> <p>14 is \$1,100 an hour.</p> <p>15 Q. Okay. And to date, you've been</p> <p>16 paid -- or you've charged approximately</p> <p>17 somewhere in the low six figures for your</p> <p>18 work here; is that right?</p> <p>19 A. I don't believe so. I believe</p> <p>20 that I've been paid about \$76,000 to date.</p> <p>21 Q. Okay. And that includes</p> <p>22 everything through now?</p> <p>23 A. Well, no. I've spent hours</p> <p>24 working on this case in between when my</p> <p>25 reports were issued and the -- and this</p>

<p style="text-align: right;">Page 70</p> <p>1 deposition. So I've put additional time in.</p> <p>2 Q. Right.</p> <p>3 So at \$1,100 an hour, you're</p> <p>4 going to be over \$100,000 by the end of the</p> <p>5 day for sure, right?</p> <p>6 A. I would expect so. I expect</p> <p>7 that I'd be compensated for the hours that</p> <p>8 I've put in with regard to the effort, and</p> <p>9 that -- and my -- I would be compensated at</p> <p>10 the same rate that I'm compensated for other</p> <p>11 activities.</p> <p>12 Q. Okay. Earlier I asked you</p> <p>13 about when you expressed in writing that you</p> <p>14 had an opinion that acetaminophen caused ASD</p> <p>15 and autism.</p> <p>16 Do you recall those questions?</p> <p>17 A. Yes, I do.</p> <p>18 Q. Okay. And the first time you</p> <p>19 put it in writing was in your rebuttal</p> <p>20 report; is that right?</p> <p>21 A. That's correct.</p> <p>22 Q. Okay. And in your rebuttal</p> <p>23 report, you purport to do a causation</p> <p>24 analysis based on human literature, right?</p> <p>25 A. Yes. In my rebuttal report,</p>	<p style="text-align: right;">Page 72</p> <p>1 correct?</p> <p>2 A. That's correct.</p> <p>3 Q. You just chose not to do it the</p> <p>4 first time, right?</p> <p>5 A. No. So I had reviewed all of</p> <p>6 the relevant information. I had had</p> <p>7 conversations with other experts to provide</p> <p>8 additional information. I utilized all of my</p> <p>9 scientific and medical background and</p> <p>10 knowledge as well and was able to form an</p> <p>11 opinion prior to my rebuttal report.</p> <p>12 In my initial amended expert</p> <p>13 report, I didn't have adequate time to</p> <p>14 perform a weight-of-the-evidence analysis for</p> <p>15 each of the individual articles that I had</p> <p>16 reviewed. And because I didn't have time to</p> <p>17 perform that weight-of-the-evidence analysis</p> <p>18 for each of the individual studies, I left it</p> <p>19 out.</p> <p>20 Q. Okay. And in your prior expert</p> <p>21 work, in Abilify, for example, you also</p> <p>22 rendered causation opinions, right?</p> <p>23 A. That's correct.</p> <p>24 Q. Okay. And your definition of</p> <p>25 causation at that point in time was that you</p>
<p style="text-align: right;">Page 71</p> <p>1 you know, I perform a Bradford Hill analysis,</p> <p>2 so it -- which is a methodology to be able to</p> <p>3 incorporate the information from the various</p> <p>4 studies that I've reviewed, yes.</p> <p>5 Q. And you just decided,</p> <p>6 Dr. Hollander, that you should do a Bradford</p> <p>7 Hill analysis in rebuttal; is that right?</p> <p>8 MR. DOVEL: The way that's</p> <p>9 phrased, that appears to call for</p> <p>10 privileged information. I'm going to</p> <p>11 ask you to rephrase that, if you</p> <p>12 could, so you're not requesting any</p> <p>13 privileged information.</p> <p>14 QUESTIONS BY MR. MURDICA:</p> <p>15 Q. Dr. Hollander, you didn't do a</p> <p>16 Bradford Hill analysis in your initial</p> <p>17 report; is that correct?</p> <p>18 A. That's correct.</p> <p>19 Q. And you did in your rebuttal</p> <p>20 report for the first time, correct?</p> <p>21 A. That's correct.</p> <p>22 Q. The information that you used</p> <p>23 for the Bradford Hill analysis in your</p> <p>24 rebuttal report was available six weeks</p> <p>25 earlier when you issued your initial report,</p>	<p style="text-align: right;">Page 73</p> <p>1 gather -- you need to have information from a</p> <p>2 broad range of sources that's all consistent,</p> <p>3 correct?</p> <p>4 A. Well --</p> <p>5 MR. DOVEL: Objection. Form.</p> <p>6 THE WITNESS: -- consistency is</p> <p>7 one important characteristic to be</p> <p>8 able to weight the evidence. It's one</p> <p>9 of the factors in a Bradford Hill</p> <p>10 analysis.</p> <p>11 QUESTIONS BY MR. MURDICA:</p> <p>12 Q. And Dr. Hollander believes,</p> <p>13 sitting here right now, that the information</p> <p>14 on acetaminophen exposure during pregnancy</p> <p>15 and the outcomes of ASD and ADHD are</p> <p>16 consistent, correct?</p> <p>17 A. That's right. In applying the</p> <p>18 Bradford Hill factors and reviewing the issue</p> <p>19 of consistency, yes, the available evidence</p> <p>20 supports consistency.</p> <p>21 MR. WATTS: Hey, Jim, we've</p> <p>22 been going about an hour. Whenever</p> <p>23 you get to a --</p> <p>24 MR. MURDICA: Sure, we can take</p> <p>25 a break.</p>

<p style="text-align: right;">Page 74</p> <p>1 VIDEOGRAPHER: The time right 2 now is 10:51 a.m. We are off the 3 record. 4 (Off the record at 10:51 a.m.) 5 VIDEOGRAPHER: The time right 6 now is 11:05 a.m. We are back on the 7 record. 8 QUESTIONS BY MR. MURDICA: 9 Q. Dr. Hollander, are you ready to 10 proceed? 11 A. Yes, I am. 12 Q. Okay. Dr. Hollander, I take it 13 from your testimony in our last session that 14 you don't believe that the MMR vaccine causes 15 ADHD; is that fair? 16 A. That's correct. 17 Q. Okay. You don't believe that 18 the MMR vaccine causes autism; is that fair? 19 A. That's correct. 20 Q. Okay. And if I asked you the 21 same questions with regard to thimerosal, 22 does Dr. Hollander believe that thimerosal 23 causes autism or ADHD? 24 A. Well, thimerosal causes a range 25 of developmental problems. I haven't</p>	<p style="text-align: right;">Page 76</p> <p>1 Q. Okay. And if Dr. Hollander is 2 testifying that maternal diabetes can be a 3 risk factor for ADHD, what you really mean is 4 that has a causal role in development of some 5 ADHD. 6 Fair? 7 A. I think it's fair that there's 8 elevated risk of the outcome associated with 9 the exposure. 10 Q. Okay. And by the way, in 11 your -- in your work with patients, are you 12 mostly treating them or are you also trying 13 to determine the cause of their presentation? 14 A. Well, I would say in a routine 15 clinical practice that, you know, one 16 important role is to help manage the 17 condition and the symptoms that decrease the 18 distress and the, you know, functional 19 impairment. So treatment is an important 20 component, but not the only component. 21 Q. Okay. And, Dr. Hollander, part 22 of my question is do you seek to identify -- 23 let's say you have a patient that you've 24 diagnosed with ADHD. 25 Do you, Dr. Hollander, seek to</p>
<p style="text-align: right;">Page 75</p> <p>1 specifically studied in detail thimerosal and 2 ASD and ADHD, but I'm not aware that 3 that's -- well, I haven't -- I haven't 4 studied that issue. 5 Q. Okay. So sitting here today, 6 Dr. Hollander would not say that thimerosal 7 causes ASD or ADHD; is that fair? 8 A. I would say it's fair at this 9 time that I don't have an opinion of it, and 10 I don't -- I don't have a belief at this 11 point that thimerosal causes it, but I 12 haven't studied it. 13 Q. Okay. Sitting here today, does 14 Dr. Hollander believe that SSRIs cause ADHD? 15 A. No. 16 Q. Okay. Sitting here today, does 17 Dr. Hollander believe that SSRIs cause 18 autism? 19 A. No. 20 Q. Okay. Sitting here today, do 21 you believe that maternal diabetes during 22 pregnancy can cause ADHD? 23 A. Well, yes, I do believe that 24 maternal diabetes can be a risk factor for 25 ADHD.</p>	<p style="text-align: right;">Page 77</p> <p>1 identify for the patient the cause of their 2 ADHD? 3 A. Well, I do seek to identify 4 contributing factors that could either 5 increase the, you know, the distress or 6 impair the functioning. Yes, I do try to 7 determine that and then intervene. 8 Q. For example, Dr. Hollander, do 9 you send your patients that you've diagnosed 10 for genetic testing? 11 A. I may, yes. 12 Q. Okay. Do you do differential 13 diagnoses on the causes of their 14 presentation? 15 A. Yes. 16 Q. Okay. And so you know how to 17 do a differential diagnosis, right? 18 A. Yeah, that's part of my routine 19 clinical practice, of course. 20 Q. Anything that you consider as a 21 possible -- as -- in the etiology of the 22 presentation of the patient has to be 23 something that you rule in as even capable of 24 causing the condition, correct? 25 A. Well, there's part of</p>

<p style="text-align: right;">Page 78</p> <p>1 differential diagnoses, yeah. You want to 2 consider other conditions or factors that can 3 contribute to the presentation of the 4 illness, and you want to, you know, try to 5 determine whether or not those conditions are 6 playing a role or not. 7 Q. Okay. So first, you rule in 8 all of the things that could be a potential 9 cause of what you're seeing, right? 10 A. Well, you consider, yeah, 11 different potential causes or conditions. 12 Q. And you don't consider causes 13 that aren't potential causes, right? 14 A. I'm not sure I follow that. 15 Q. Let me ask a better question. 16 You just testified that the MMR 17 vaccine can't cause autism, right? 18 A. Right. I said that the MMR 19 vaccine does not cause autism. 20 Q. Right. 21 So you're not going to ask a 22 patient who has autism whether or not they 23 received the MMR vaccine because it's not 24 something that you consider in your 25 differential, correct?</p>	<p style="text-align: right;">Page 80</p> <p>1 influence the effect. Or can mediate or 2 moderate the effect. 3 Q. Is there a -- well, this 4 question is about ADHD. 5 A. Okay. 6 Q. For ADHD, according to 7 Dr. Hollander, is there a presentation of 8 ADHD that's pathognomonic for the cause? 9 A. Well, there are -- well, there 10 are multiple factors that need to be 11 considered but that there's no single cause 12 for all individuals with ADHD. It's 13 multifactorial. 14 Q. Right. 15 And my question was a little 16 different. I was asking whether there's 17 something that's pathognomonic. So let me 18 try asking a better question. 19 If you see an individual that 20 you've diagnosed with ADHD, can Dr. Hollander 21 say, oh, I can tell by this presentation that 22 it was caused by this one thing? 23 Do you understand my question? 24 A. I guess you're saying is there 25 a single factor that can be -- fully account</p>
<p style="text-align: right;">Page 79</p> <p>1 A. That would be correct. 2 Q. Okay. And so my question was, 3 the only things you would consider as a 4 possible cause are factors that are actually 5 capable of being causal, correct? 6 A. Well, I would be interested in 7 causal factors. I'd also be interested in 8 mediators and moderators. 9 Q. Okay. So you'd put mediators 10 and moderators on your differential 11 diagnosis? 12 A. Yes. 13 Q. Okay. And to your knowledge, 14 is that a standard way to do differential 15 diagnosis? 16 A. Well, if you're going to do a 17 comprehensive differential diagnosis, you'd 18 want to consider those factors. 19 Q. Okay. Including -- so you 20 would put mediators and moderators as 21 potential causes in a differential diagnosis? 22 A. No, I wouldn't -- no. So 23 mediators and moderators are not causes. 24 They are factors that can be related to both 25 the exposure and the outcome and can</p>	<p style="text-align: right;">Page 81</p> <p>1 for ADHD in a particular individual? 2 Q. What I'm saying is, is there 3 any particular presentation of an individual 4 that Dr. Hollander says, oh, I know because 5 of exactly how this looks that the cause had 6 to be Y? 7 A. Right. So you're saying is 8 there like a phenotype -- 9 Q. Right. 10 A. -- that's associated with a 11 specific cause? 12 Q. Yes. 13 A. Well, I think for ADHD and, you 14 know, idiopathic causes of ADHD, there are 15 multiple different factors and cofactors that 16 contribute to the symptoms and the syndrome. 17 So that for most individuals, no, there's not 18 a specific phenotype that's associated with a 19 specific cause. 20 However, there can be different 21 factors that contribute to the causation, and 22 those factors may differ from individual to 23 individual. 24 Q. Dr. Hollander, if I asked you 25 that question about autism, would you give me</p>

<p style="text-align: right;">Page 82</p> <p>1 the same answer?</p> <p>2 MR. DOVEL: Objection. Form.</p> <p>3 THE WITNESS: I might give you</p> <p>4 a different answer in that, you know,</p> <p>5 with regards to autism, there are</p> <p>6 known sort of syndromal causes of</p> <p>7 autism. So those are conditions where</p> <p>8 there may be a single genetic factor</p> <p>9 that's associated with a particular</p> <p>10 phenotype. And then when you look at</p> <p>11 the phenotype, you can also diagnose</p> <p>12 them as having ASD because they'd have</p> <p>13 the criteria.</p> <p>14 So in those cases of syndromal</p> <p>15 forms of autism like Fragile X</p> <p>16 syndrome or Prader-Willi Syndrome, for</p> <p>17 example, there may be a single cause</p> <p>18 associated with the ASD in those</p> <p>19 particular individuals.</p> <p>20 QUESTIONS BY MR. MURDICA:</p> <p>21 Q. Right.</p> <p>22 So Dr. Hollander could look at</p> <p>23 a patient with -- a particular autism patient</p> <p>24 and say, oh, those are the factors that show</p> <p>25 me that Fragile X is probably the cause,</p>	<p style="text-align: right;">Page 84</p> <p>1 condition is caused by genetics?</p> <p>2 A. You know, it's a very</p> <p>3 interesting question, and I think that the</p> <p>4 evidence actually points in two different</p> <p>5 directions with regards to that. So that</p> <p>6 there is some evidence that the more</p> <p>7 restrictive you make the phenotype, the</p> <p>8 stronger the genetic variation or</p> <p>9 contribution.</p> <p>10 However, the opposite is also</p> <p>11 true because, you know, there are traits</p> <p>12 actually that run within families, like the</p> <p>13 broader autism phenotype, that seem to be</p> <p>14 familial and/or genetic that are actually</p> <p>15 broader rather than more restrictive aspects</p> <p>16 of the phenotype.</p> <p>17 So it's very interesting</p> <p>18 because it could work in both different</p> <p>19 directions.</p> <p>20 Q. Okay. And I take it,</p> <p>21 Dr. Hollander, you don't know how Dr. Cabrera</p> <p>22 answered that question when I asked him?</p> <p>23 A. That's correct, I don't know</p> <p>24 how he answered that question.</p> <p>25 Q. Did you review his report and</p>
<p style="text-align: right;">Page 83</p> <p>1 let's go get a genetic test.</p> <p>2 Right?</p> <p>3 A. Well, I think it would be the</p> <p>4 other way around. So the person may present</p> <p>5 with the phenotype, then they might get</p> <p>6 genetic testing, and then that genetic</p> <p>7 testing would confirm the diagnosis.</p> <p>8 Q. Okay. And in that specific</p> <p>9 example you just talked about, that would be</p> <p>10 a purely genetic cause, correct?</p> <p>11 A. Well, I would say yes and no.</p> <p>12 And so even in these syndromal forms of ASD</p> <p>13 like Fragile X or Prader-Willi Syndrome,</p> <p>14 there's still a lot of heterogeneity in terms</p> <p>15 of the presentation of the phenotype. So it</p> <p>16 does differ.</p> <p>17 And that there -- there can be</p> <p>18 factors that modify the presentation of the</p> <p>19 illness. So even in these syndromal forms of</p> <p>20 ASD, that there can be other factors that</p> <p>21 shape the expression of the phenotype.</p> <p>22 Q. Dr. Hollander, do you agree</p> <p>23 that for -- start with autism -- for autism,</p> <p>24 the more severe the presentation of the</p> <p>25 autistic symptoms, the more likely that the</p>	<p style="text-align: right;">Page 85</p> <p>1 his rebuttal report?</p> <p>2 A. Yes, I did.</p> <p>3 Q. Okay. Did you see that</p> <p>4 Dr. Cabrera holds the opinion that the more</p> <p>5 severe the autistic symptoms, the more likely</p> <p>6 it is to be caused by genetics?</p> <p>7 MR. DOVEL: Objection. Form.</p> <p>8 THE WITNESS: I believe that he</p> <p>9 was responding to a point that had</p> <p>10 been made by Wendy Chung with regards</p> <p>11 to that. And I do think that in his</p> <p>12 rebuttal report he acknowledged that</p> <p>13 the tighter and tighter the</p> <p>14 restriction in the phenotype, that</p> <p>15 there could be more and more sort of</p> <p>16 genetic heritability.</p> <p>17 Whereas if you broaden the</p> <p>18 phenotype somewhat, then do you have</p> <p>19 more and more and more environmental</p> <p>20 heritability contributing factors.</p> <p>21 QUESTIONS BY MR. MURDICA:</p> <p>22 Q. And do you disagree with him on</p> <p>23 that point?</p> <p>24 A. Well, I do disagree with him</p> <p>25 with regards to this one idea, which is that</p>

<p style="text-align: right;">Page 86</p> <p>1 with regards to the -- so I think it actually 2 can work both ways. 3 So on the one hand, the more -- 4 the more restrictive you make the phenotype, 5 there can be more genetic heritability. But 6 I also think that you get that genetic 7 heritability even in the broader phenotype, 8 which seems counterintuitive but is also 9 true. 10 Q. Dr. Hollander, I'm going to ask 11 you some more questions about what can and 12 cannot cause ADHD. 13 Okay? 14 A. (Witness nods head.) 15 Q. According to Dr. Hollander, can 16 a maternal fever -- untreated maternal fever 17 during pregnancy result in a child with ADHD 18 as a cause? 19 A. Well, yes. I mean, untreated 20 maternal fever, particularly the higher the 21 fever and the longer the period of time, can 22 increase the risk for having 23 neurodevelopmental outcomes, including ADHD 24 or ASD or neurodevelopmental disorders. 25 Q. According to Dr. Hollander, can</p>	<p style="text-align: right;">Page 88</p> <p>1 air pollution and neurodevelopmental 2 disorders. There's increased relative risk. 3 But I haven't applied, you know, like a 4 standardized methodology in order to develop 5 an opinion with regards to causation. 6 Q. Okay. So sitting here today, 7 Dr. Hollander wouldn't be able to tell us 8 whether air pollution exposure to the mother 9 can cause ADHD in the child. 10 Fair? 11 A. I think it -- yeah, given that 12 I haven't really applied a kind of a 13 standardized methodology in order to 14 interpret the literature. All I can say is 15 that there's an association, but I'm not sure 16 that I could make a definitive statement 17 about causation. 18 Q. And not to be tedious, but the 19 same question. Can air pollution exposure to 20 the mother during pregnancy result in ASD in 21 the child, according to Dr. Hollander today? 22 A. I think I would have the same 23 answer. 24 Q. Okay. Dr. Hollander, can 25 premature birth cause ADHD in the child?</p>
<p style="text-align: right;">Page 87</p> <p>1 maternal obesity cause ADHD in the offspring? 2 A. Yeah. Maternal obesity, again, 3 can be another factor that increases relative 4 risk for, you know, ADHD as well as ASD and 5 neurodevelopmental disorders. 6 Q. Okay. Can air pollution, 7 according to Dr. Hollander, air pollution 8 exposure in the mother during pregnancy cause 9 ADHD and autism? 10 A. There -- I mean, there are 11 studies that suggest that exposure to air 12 pollution increases the relative risk for 13 neurodevelopmental disorders. 14 Q. Okay. So would Dr. Hollander 15 consider that as a potential cause of an 16 outcome of autism and ADHD in a child? 17 A. I haven't, you know, studied 18 that in detail, and I haven't, you know, 19 applied either weight of the evidence or 20 haven't looked at the material and then tried 21 to use standardized methodology like Bradford 22 Hill in order to understand causation. 23 So I -- I'm not -- I can tell 24 you that there is some evidence for an 25 association between, you know, pollution or</p>	<p style="text-align: right;">Page 89</p> <p>1 A. Premature birth can be a factor 2 that's associated with an increased relative 3 risk of neurodevelopmental outcomes. 4 Q. Okay. And I think I understand 5 the distinction you're drawing, 6 Dr. Hollander. 7 A. Yeah. 8 Q. Are you willing to say that 9 prematurity -- a premature baby, the 10 prematurity itself can be a cause of the ADHD 11 or no? 12 A. I'm not prepared to offer an 13 opinion in terms of causation, but I can say 14 that there's a -- there's an association. 15 Q. Okay. And if I asked you -- 16 I'm going to ask you the same question on 17 autism. 18 A. Right. 19 Q. Does premature birth cause 20 autism? 21 A. I mean, I guess my answer is 22 that there's probably an increased relative 23 risk, but that I'm not sure that I could make 24 a comment regarding causation. 25 Q. Okay. And when I'm asking</p>

<p style="text-align: right;">Page 90</p> <p>1 these questions, Dr. Hollander, and you're</p> <p>2 saying they cause an increased risk but you</p> <p>3 can't say causation, you would tell me if you</p> <p>4 believed they weren't possibly a cause.</p> <p>5 You're not saying that, right?</p> <p>6 A. I'm not -- I'm not saying that</p> <p>7 they -- I'm saying that, you know, I haven't</p> <p>8 reviewed the literature and applied</p> <p>9 standardized methods and looked at things</p> <p>10 like confounders in order to make a causation</p> <p>11 statement, yes.</p> <p>12 Q. Okay. And just to put further</p> <p>13 clarity on that. If you were trying to</p> <p>14 figure out the etiology of autism in one of</p> <p>15 your patients, for some reason you wanted to</p> <p>16 do that, and you found out they were born</p> <p>17 premature, you wouldn't -- you wouldn't rule</p> <p>18 that out as a cause, right?</p> <p>19 A. I could -- I would say that it</p> <p>20 could potentially be a risk factor, so it</p> <p>21 could be a contributing factor.</p> <p>22 Q. Right.</p> <p>23 So you wouldn't -- without</p> <p>24 more, you wouldn't rule it out. You would</p> <p>25 consider it on the differential.</p>	<p style="text-align: right;">Page 92</p> <p>1 A. Well, so it's been reported</p> <p>2 that low birth weight increases the risk for</p> <p>3 that particular outcome, right?</p> <p>4 But in order to determine</p> <p>5 whether or not the elevated relative risk</p> <p>6 causes it, you'd have to be able to look at</p> <p>7 that and establish that it's a causal</p> <p>8 relationship between the exposure and the</p> <p>9 outcome.</p> <p>10 Q. Okay. And for these things I'm</p> <p>11 asking about for premature birth, low birth</p> <p>12 weight, air pollution, you -- it's just that</p> <p>13 you haven't done that.</p> <p>14 Fair?</p> <p>15 A. No, I'm drawing a distinction</p> <p>16 between association and causation.</p> <p>17 Q. Okay. And my question,</p> <p>18 Dr. Hollander, is, I understand you're saying</p> <p>19 there's an association. Correct me if I'm</p> <p>20 wrong, but the reason Dr. Hollander can't say</p> <p>21 that it's causal is because you haven't done</p> <p>22 a full analysis for causation, right?</p> <p>23 A. Well, that's one reason, is</p> <p>24 that I haven't done a full analysis for</p> <p>25 causation. And also, I haven't studied the</p>
<p style="text-align: right;">Page 91</p> <p>1 Fair?</p> <p>2 A. I would consider it as a factor</p> <p>3 that could contribute to the -- you know, the</p> <p>4 outcome.</p> <p>5 Q. Okay. Dr. Hollander, low birth</p> <p>6 weight, can low birth weight cause ADHD in</p> <p>7 the -- in the child?</p> <p>8 A. Well, I would say that a low</p> <p>9 birth weight is a factor that can increase</p> <p>10 the risk for ADHD as an outcome.</p> <p>11 Q. Does low birth weight increase</p> <p>12 the risk for autism as an outcome in a child?</p> <p>13 A. I believe that that -- that is</p> <p>14 a factor that has some impact on the relative</p> <p>15 risk.</p> <p>16 Q. Okay. And I don't want to put</p> <p>17 words in your mouth, but the reason</p> <p>18 Dr. Hollander isn't saying that low birth</p> <p>19 weight can cause autism and ADHD is just</p> <p>20 because you haven't done a Bradford Hill.</p> <p>21 Is that what you're saying?</p> <p>22 A. No.</p> <p>23 Q. Okay. What prevents you from</p> <p>24 saying that low birth weight can cause</p> <p>25 autism?</p>	<p style="text-align: right;">Page 93</p> <p>1 literature to determine whether or not there</p> <p>2 were methods employed to be able to exclude</p> <p>3 either known or unknown type confounders that</p> <p>4 may be contributing to the association.</p> <p>5 Q. And that's an important part in</p> <p>6 analyzing an association, to exclude known</p> <p>7 and unknown confounders, correct?</p> <p>8 A. Well, yes. I mean, if you want</p> <p>9 to determine the relationship between</p> <p>10 exposure and an outcome, you want to show</p> <p>11 that that relationship persists even when you</p> <p>12 do various things to try to control for</p> <p>13 various known or unknown confounders.</p> <p>14 Q. And you can also try to do an</p> <p>15 analysis to control for bias, right?</p> <p>16 A. Right. That -- that's</p> <p>17 something that you do want to consider. And</p> <p>18 there are different sources of bias, and you</p> <p>19 want to be able to control for that bias</p> <p>20 in multiple different ways.</p> <p>21 Q. Okay. Back to the risk</p> <p>22 factors.</p> <p>23 Do you believe that -- does</p> <p>24 Dr. Hollander believe that difficulty during</p> <p>25 childbirth can cause ADHD?</p>

<p>Page 94</p> <p>1 A. Well, again, I would respond 2 that difficulties during childbirth can be 3 associated with an increased risk of the 4 outcome. 5 Q. And the same question for 6 autism, can difficulty during childbirth 7 cause autism in the child? 8 A. Well, again, I wouldn't say -- 9 I wouldn't say that. All I would say is that 10 the difficulties in childbirth can be 11 associated with increased relative risk for 12 that outcome. 13 Q. Dr. Hollander, does maternal 14 hypertensive disorder have the potential to 15 cause ADHD in a child? 16 A. Well, I mean, I haven't studied 17 that in detail. I haven't -- I haven't 18 really looked at the literature with regards 19 to maternal hypertension. 20 I know that maternal 21 hypertension in and of itself can be 22 associated with different kinds of negative 23 outcomes, so it is possible that it could be 24 associated with things like birth trauma or 25 premature birth or -- and that those -- so</p>	<p>Page 96</p> <p>1 child? 2 A. Yes, preeclampsia can be a 3 factor that increases relative risk of the 4 outcome. 5 Q. Okay. Can preeclampsia cause 6 ADHD in the child? 7 A. I don't know whether or not it 8 can cause ADHD in the outcome for the same 9 reasons, both in terms of whether or not 10 adequate confounders have been controlled for 11 and the relative risk persists, and also 12 whether or not standardized methodology have 13 been utilized in order to determine 14 causation. 15 Q. Okay. And, Dr. Hollander, that 16 was about ADHD, and I appreciate the answer. 17 I'm going to ask you the same question about 18 autism. 19 Can preeclampsia cause autism 20 in a child? 21 A. That I've -- I think I would 22 have the same response. 23 Q. Okay. Can childhood eczema 24 cause ADHD, according to Dr. Hollander? 25 A. Well, childhood eczema, you</p>
<p>Page 95</p> <p>1 it's -- I mean, it's possible that it could 2 be a factor or a cofactor associated with 3 increased relative risk. 4 Q. Okay. So sitting here today, 5 Dr. Hollander, you can't say whether maternal 6 hypertensive disorder during pregnancy can 7 cause or increase the risk of ADHD in the 8 child? 9 A. Well, I believe that my 10 response would be similar to the other 11 responses, again, that it -- you know, it may 12 be associated with an elevated relative risk. 13 But, again, because I haven't employed 14 methods to determine whether or not it could 15 be causal, and because I haven't seen whether 16 or not, you know, different sources of bias 17 or potential known or unknown confounders 18 have been adjusted for, it's hard to make a 19 statement with regards to causality. 20 Q. Okay. And maternal 21 hypertensive disorder, is that preeclampsia? 22 A. That can contribute to 23 preeclampsia. 24 Q. Okay. And do you associate 25 preeclampsia with the outcome of ADHD in a</p>	<p>Page 97</p> <p>1 know, can be like a -- you know, an immune 2 inflammatory condition. And immune 3 inflammatory conditions during pregnancy 4 could -- during pregnancy could be associated 5 with things like maternal immune activation, 6 which could be a risk factor increasing the 7 relative risk for the outcome. 8 Q. Okay. So if I understood you 9 correctly, childhood eczema via inflammation 10 could be an -- be a risk factor for ADHD in 11 the child? 12 A. Well, let me modify that. 13 So childhood eczema -- there's 14 an issue of temporality here. So childhood 15 eczema, you're implying that this is 16 something that's occurring in the child 17 post-birth, right? So that wouldn't be a 18 causative factor because of the issue of 19 temporality. It wouldn't occur during the 20 time of fetal development, so that it 21 wouldn't -- it wouldn't -- from a temporality 22 standpoint, it wouldn't be causative. 23 Q. Okay. Dr. Hollander, from a 24 temporality standpoint, what is the cutoff in 25 development from when a condition can no</p>

<p style="text-align: right;">Page 98</p> <p>1 longer cause -- an exposure can no longer 2 cause ADHD or autism?</p> <p>3 A. Well, if -- I mean, if you're 4 looking at maternal exposure during 5 pregnancy, and that's the exposure, and the 6 outcome is neurodevelopmental disorders, then 7 the temporality, or the exposure, would occur 8 during pregnant -- pregnancy.</p> <p>9 Q. Okay. Let me put a finer point 10 on this.</p> <p>11 I think I just heard your 12 testimony that childhood eczema, in other 13 words, after birth, is too late to cause 14 ADHD, correct?</p> <p>15 A. Well, it's a -- so I guess -- 16 here is -- here is a caveat, but, yes, in 17 terms of temporality of exposure, yeah, it 18 wouldn't be in the window of maternal 19 exposure, so it wouldn't be associated with a 20 maternal exposure being a...</p> <p>21 However, you know, it's 22 possible that, as you know, that, you know, 23 autoimmune disorders can run in families. So 24 if you have a family where there are multiple 25 autoimmune disorders, then it's possible that</p>	<p style="text-align: right;">Page 100</p> <p>1 a long-acting compound, for example. Then 2 it's possible that the mother would still 3 have measurable, you know, plasma levels 4 during pregnancy.</p> <p>5 So in that kind of a case, it 6 could be.</p> <p>7 Q. Okay. And so let me put a 8 finer point on my question.</p> <p>9 Let's say there's a medication 10 with less than 12 hours of half-life. 11 Exposure three months before pregnancy is not 12 going to affect the fetus, correct?</p> <p>13 A. No, I would say if the -- I 14 mean, if you're looking at a longer period of 15 time and a drug with a short half-life, then 16 it would be less likely that an earlier 17 exposure would be associated with maternal 18 exposure unless -- or here's the other -- I 19 mean, just off the top of my head -- unless 20 it was -- unless that exposure beforehand was 21 somehow a marker of the mother's continuing 22 exposure during the pregnancy.</p> <p>23 So you might make the argument, 24 well, if somebody is taking something prior 25 to pregnancy, well, maybe there's a higher</p>
<p style="text-align: right;">Page 99</p> <p>1 it increases the risk of the mother having a 2 maternal autoimmune disorder during 3 pregnancy. So it could be like a -- you 4 know, a marker.</p> <p>5 But -- so one of the ways to 6 determine that is like negative exposures, 7 right? So you look at the temporality of the 8 exposure, and then you look at the exposures 9 outside of that window as a control. So 10 that's why many of these studies have looked 11 at negative exposure four years before 12 pregnancy or four years after pregnancy as 13 a negative control in order to control for 14 that.</p> <p>15 Q. Okay. Dr. Hollander, an 16 exposure three months before pregnancy to a 17 medication is not going to cause ADHD or 18 autism in offspring, correct?</p> <p>19 A. Well, I would say it would be 20 less likely; however, it's still possible, 21 and I'll give you a possibility.</p> <p>22 Let's say the mother was a -- 23 administered a compound that, you know, 24 stored in the fat and persisted for a long 25 time. Let's say the mother was injected with</p>	<p style="text-align: right;">Page 101</p> <p>1 likelihood that it could still be taken 2 during pregnancy. So maybe it would be an 3 indirect marker, but that -- you wouldn't 4 think -- no, for the -- I mean, if it's 5 not -- if it's not in the mother's plasma, 6 it's not a compound that's present during 7 pregnancy, then you wouldn't think that that 8 exposure would be associated with the 9 outcome.</p> <p>10 Q. Okay. And, Dr. Hollander, 11 you're not a teratologist, right?</p> <p>12 A. No.</p> <p>13 Q. But you understand what 14 teratology is, right?</p> <p>15 A. Yes, I'm familiar with the 16 principles and practices.</p> <p>17 Q. Okay. And do you agree that in 18 general, exposures in the first two weeks of 19 pregnancy are all-or-nothing events that 20 either kill the embryo or don't affect it?</p> <p>21 MR. DOVEL: Objection. Form. 22 QUESTIONS BY MR. MURDICA:</p> <p>23 Q. Do you understand my question?</p> <p>24 A. Well, I am aware that exposures 25 early on can be associated with higher risks</p>

<p style="text-align: right;">Page 102</p> <p>1 of like a termination of the pregnancy, 2 right? So -- and then if the pregnancy is 3 terminated, then you wouldn't have the 4 outcome. 5 Q. Right. 6 Do you remember seeing in 7 Dr. Cabrera's report the little chart that 8 showed the first 14 days are exposures that 9 either terminate the pregnancy or don't? 10 A. I do recall seeing that chart. 11 Q. Okay. And I guess what I'm 12 trying to get at, Dr. Hollander, is, your 13 window of exposure for something that can 14 cause ADD -- ADHD and autism -- 15 A. Right. 16 Q. -- is when the mother is 17 actually pregnant up to the time of 18 childbirth; is that correct? 19 A. That's correct. 20 Q. Okay. Back to my question on 21 what can cause ADHD. 22 Can low maternal serum 23 vitamin D cause ADHD in the child? 24 A. Well, it is possible that, you 25 know, maternal nutritional status can play a</p>	<p style="text-align: right;">Page 104</p> <p>1 overall relative risk, or the greater 2 likelihood of the expression of the full 3 phenotype. 4 Cofactors may be things that 5 directly interact then with other factors. 6 So, for example, if you have nutritional -- 7 poor nutrition, for example, or other forms 8 of stress on the mother that could deplete 9 things like glutathione, that could be like a 10 cofactor. 11 So that, let's say, you have an 12 exposure to a compound that has an impact on, 13 let's say, oxidative stress, but it occurs in 14 a setting where you've depleted a particular 15 antioxidant, then it would be a cofactor. So 16 they would be working in concert together, 17 and they wouldn't just be independent 18 factors. 19 Q. Okay. So sitting here today, 20 Dr. Hollander would not say that maternal low 21 vitamin D can cause autism or ADHD, correct? 22 A. Well, for the reasons before, I 23 wouldn't use the word "cause." You know, I 24 might say relative risk or association. 25 Q. In order to get to causation on</p>
<p style="text-align: right;">Page 103</p> <p>1 role as a risk factor for neurodevelopmental 2 disorders and that, you know, nutritional 3 factors that have an impact on things like 4 oxidative stress could potentially be risk 5 factors. 6 Q. Okay. So would Dr. Hollander 7 consider vitamin D deficiency, a low serum 8 vitamin D, as a potential cause of ADHD in a 9 child? 10 A. Again, I wouldn't use the word 11 "cause," but I would -- I would say that it's 12 possible that that could be -- there could be 13 a risk factor or an association, and it could 14 be a cofactor. 15 So poor nutritional status 16 could be a cofactor along with exposure to 17 other compounds that may have an additive 18 effect in terms of impacting the outcome. 19 Q. And, Dr. Hollander, when you 20 say "cofactor," do you mean it could be a 21 contributing cause to the outcome? 22 A. Not exactly, no, because -- so 23 contributing cause would be that there would 24 be, you know, multiple hits, and then the 25 more hits that you have, the higher the</p>	<p style="text-align: right;">Page 105</p> <p>1 a question like that, Dr. Hollander, you 2 would need to do a full weight-of-the- 3 evidence analysis, correct? 4 A. Well, again, you'd want to look 5 to see whether there are other factors that 6 influence the association, right? You would 7 want to -- you'd want to control for other 8 factors that influence the association, and 9 then you'd want to apply standardized 10 methodology in order to determine causation. 11 Yeah. 12 Q. Okay. And it's just that we -- 13 no one has asked you to do that, right? 14 So sitting here today, you 15 can't say whether it can be causal. 16 Fair? 17 MR. DOVEL: Objection. Form. 18 THE WITNESS: Well, I guess I'm 19 saying two things. One is, I 20 certainly haven't done that, but I'm 21 also not aware in the literature of 22 that as well or whether others have 23 done that. 24 QUESTIONS BY MR. MURDICA: 25 Q. Okay. But you don't know</p>

<p style="text-align: right;">Page 106</p> <p>1 whether the literature exists or not, right?</p> <p>2 A. I believe that the literature</p> <p>3 has looked at issues in terms of association,</p> <p>4 but I don't know whether or not those studies</p> <p>5 that looked at association adequately</p> <p>6 controlled for, again, you know, various</p> <p>7 factors like confounders. And so -- and/or</p> <p>8 whether or not, you know, anybody has applied</p> <p>9 standard methodology to determine causation.</p> <p>10 Q. Dr. Hollander, have you -- do</p> <p>11 you have an opinion of whether advanced</p> <p>12 maternal age can cause autism and ADHD?</p> <p>13 A. Well, I do know that there's</p> <p>14 pretty good evidence, actually, that both</p> <p>15 maternal and paternal age can be a risk</p> <p>16 factor for increasing the risk of</p> <p>17 neurodevelopmental disorders, including ASD</p> <p>18 and ADHD.</p> <p>19 Q. Okay. And paternal age was</p> <p>20 going to be my next question.</p> <p>21 A. Right.</p> <p>22 Q. Dr. Hollander, I take it from</p> <p>23 your answer that the risk factors that -- you</p> <p>24 haven't done an analysis as to whether</p> <p>25 advanced maternal or paternal age is</p>	<p style="text-align: right;">Page 108</p> <p>1 the father or the mother ages, you know, you</p> <p>2 have sperm or eggs that are replicating over</p> <p>3 and over and over and over again. And the</p> <p>4 longer the period of time that that happens,</p> <p>5 the more likely that you can get problems in</p> <p>6 terms of, you know, copying the DNA, and</p> <p>7 you're more likely to get de novo mutations,</p> <p>8 actually.</p> <p>9 So, I mean, it's a very</p> <p>10 interesting idea that as a -- as an</p> <p>11 environmental factor, I guess, maternal or</p> <p>12 paternal age, it actually can influence the</p> <p>13 genetic contribution.</p> <p>14 Q. And understanding,</p> <p>15 Dr. Hollander, that you're, you know,</p> <p>16 considering this right now --</p> <p>17 A. Yeah.</p> <p>18 Q. -- are you willing to say it's</p> <p>19 causal today or not?</p> <p>20 A. I'm not able to say whether or</p> <p>21 not it's causal today.</p> <p>22 Q. Okay.</p> <p>23 How about maternal depression,</p> <p>24 Dr. Hollander? Is maternal depression</p> <p>25 causative of ADHD in the child?</p>
<p style="text-align: right;">Page 107</p> <p>1 causative for autism or ADHD.</p> <p>2 Fair?</p> <p>3 A. Well, I mean, that's a very --</p> <p>4 it's an interesting finding. It's a pretty</p> <p>5 strong finding that has been repeated.</p> <p>6 It actually -- it's interesting</p> <p>7 for a couple different reasons, but one is it</p> <p>8 informs hypotheses with regards to plausible</p> <p>9 biological mechanisms as well.</p> <p>10 Q. And I understand what you're</p> <p>11 saying, Dr. Hollander, and I'm just asking.</p> <p>12 The reason you can't -- you won't say right</p> <p>13 now that advanced maternal and paternal age</p> <p>14 is causative of autism and ADHD is because</p> <p>15 you haven't done a weight-of-the-evidence</p> <p>16 analysis and looked at it, correct?</p> <p>17 A. Well, I think that -- that --</p> <p>18 that relationship is pretty strong, that</p> <p>19 association. And I do believe that there</p> <p>20 have been attempts to look at different kinds</p> <p>21 of confounders with regards to that, and that</p> <p>22 the association persists even when</p> <p>23 controlling for certain confounders.</p> <p>24 I also think that -- again,</p> <p>25 it's interesting because it suggests that as</p>	<p style="text-align: right;">Page 109</p> <p>1 A. Well, I think it's</p> <p>2 well-documented that, you know, maternal</p> <p>3 stress and maternal psychiatric illness is</p> <p>4 not good for the baby or the fetus. However,</p> <p>5 I think that that's an area where people have</p> <p>6 looked at different kinds of confounders and</p> <p>7 tried to control for that, and there hasn't</p> <p>8 been strong evidence for causation.</p> <p>9 Q. Do you recognize,</p> <p>10 Dr. Hollander, that there's an association in</p> <p>11 studies between maternal depression and the</p> <p>12 outcomes of ADHD and autism?</p> <p>13 A. I'm aware that there's an</p> <p>14 association. I do know that people have been</p> <p>15 trying to blame the mother for long periods</p> <p>16 of time on causing autism, the whole</p> <p>17 refrigerator mother hypothesis. And that's</p> <p>18 been carried forward also to look at various</p> <p>19 kinds of maternal behavioral factors and</p> <p>20 psychiatric factors and looking at their</p> <p>21 relationship to outcome.</p> <p>22 Q. Dr. Hollander, you raise a good</p> <p>23 point. There's been several things that have</p> <p>24 been blamed as causes of autism that turned</p> <p>25 out to not be true, right?</p>

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1 A. That's true.

2 Q. Okay. One of them is what you

3 just mentioned, refrigerator mothers, the

4 theory basically that the mothers were cold

5 and didn't love their children and they

6 developed autism, right?

7 A. That's correct.

8 Q. Okay. And that -- you agree

9 that is not something that is factual, right?

10 A. No. So refrigerator mothers

11 are not the cause of autism.

12 It is possible that, you know,

13 profound deprivation, so people who are like

14 raised in orphanages and don't get any kind

15 of maternal caring, can be at increased

16 relative risk for developing

17 neurodevelopmental problems. But, no, that,

18 you know, refrigerator mothers don't cause

19 autism.

20 Q. Right.

21 And, Dr. Hollander, there was a

22 point in time in the early 20th century when

23 doctors actually said that was a cause of

24 autism, right?

25 A. That's true.

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1 Q. Okay. And we discussed this

2 earlier, but there was a point in time only

3 20 years ago when some doctors thought that

4 vaccines caused autism, right?

5 A. That's true. The theory has

6 been discredited, but there was a time when

7 some people posited that.

8 Q. Yeah.

9 And, Doctor, to make this

10 easier, I'm going through things that have

11 been attributed as causes that have been

12 discredited --

13 A. Okay.

14 Q. -- and seeing what you agree.

15 A. Okay.

16 Q. Have you -- do you know that

17 the Ferber method of --

18 A. Yeah.

19 Q. -- with children has been

20 discredited as a cause of autism after being

21 attributed as a cause?

22 A. Yeah, I agree that the Ferber

23 method doesn't cause autism.

24 Q. Dr. Hollander, are you aware

25 that there were theories with doctors saying

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1 that certain dairy products caused autism?

2 A. I am -- I am aware that some

3 people feel that like a, you know, gluten and

4 casein-free diets, for example, that those

5 can trigger inflammatory processes. And so

6 one approach is try to eliminate that, for

7 example, in the diet and see whether or not

8 it affects behavior.

9 Q. Okay. Does Dr. Hollander

10 believe that the dairy products and gluten

11 theory as a cause of autism has been

12 discredited?

13 A. Yeah, I think there's no

14 evidence that that causes autism.

15 Q. Okay. Have you seen,

16 Dr. Hollander, that there was a theory

17 posited by doctors that modern wheat, the

18 advent of modern wheat, was causing autism?

19 A. Well, the same idea again, you

20 know, like wheat can trigger inflammatory

21 processes in some people who are sensitive to

22 that. But I don't think that wheat is the

23 cause of autism.

24 Q. Okay. And cable TV was posited

25 as a cause of autism.

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1 Are you aware of that?

2 A. I'm not aware of that.

3 Q. Okay. Dr. Hollander, cable TV

4 is not a cause of autism, right?

5 A. No.

6 Q. See, the easiest question in

7 your deposition.

8 A. Okay.

9 Q. Okay. Let's talk a little bit

10 about the diagnosis rates of autism and ADHD.

11 Dr. Hollander, in your rebuttal

12 report, at one point you say they're

13 increasing, and at another point you're

14 saying they're stable throughout the world.

15 What is your opinion right now

16 about the diagnosis rates of ADHD and whether

17 they are increasing, decreasing or staying

18 flat?

19 A. Well, I disagree with your

20 statement that in my rebuttal I state that

21 the rates of ASD and ADHD are stable

22 throughout the world. I believe that I was

23 referencing a comment that Dr. Faraone said.

24 So that's where that sentence came from. It

25 wasn't from me.

<p style="text-align: right;">Page 114</p> <p>1 Yeah, I believe that in the</p> <p>2 last 20 years, you know, the rates of ASD</p> <p>3 have more -- they have quadrupled. So like a</p> <p>4 400 percent increase. And so the rates have</p> <p>5 gone from about 1 to 350 to 1 in 36.</p> <p>6 Q. You're talking about autism,</p> <p>7 Doctor?</p> <p>8 A. Autism, yeah.</p> <p>9 Q. Okay. And, Doctor, in the</p> <p>10 opinion of Dr. Hollander, does that represent</p> <p>11 an autism epidemic or just better diagnosis?</p> <p>12 A. Well, that's a good -- it's a</p> <p>13 good question, and that is a topic that has</p> <p>14 been debated in the field, whether the</p> <p>15 increase in estimates, let's say, from 1</p> <p>16 in -- just in the last 20 years, 1 in 350 to</p> <p>17 1 in 36, can be attributed solely to, you</p> <p>18 know, broadening diagnostic criteria or</p> <p>19 increased public awareness or greater</p> <p>20 screening, for example, or whether, in fact,</p> <p>21 they represent true increases. And there are</p> <p>22 different ways to try to disentangle or</p> <p>23 address that.</p> <p>24 So one of the ways to try to</p> <p>25 address that is to use standardized</p>	<p style="text-align: right;">Page 116</p> <p>1 Dr. Hollander, but what is your opinion? Is</p> <p>2 your opinion that -- we'll start with</p> <p>3 autism -- that there are genuinely more cases</p> <p>4 of autism, and it doesn't have to do with the</p> <p>5 other potential explanations that you just</p> <p>6 said?</p> <p>7 A. Well, my opinion is that there</p> <p>8 are different factors that can contribute and</p> <p>9 that need to be understood and controlled</p> <p>10 for.</p> <p>11 Q. Okay.</p> <p>12 A. So I am aware that diagnostic</p> <p>13 criteria have changed a little bit, you know,</p> <p>14 particularly with the idea in DSM-5 of</p> <p>15 looking at the spectrum as opposed to</p> <p>16 individual diagnoses, and I am aware that</p> <p>17 there's a lot more awareness now of these</p> <p>18 conditions.</p> <p>19 And I'm aware that there's more</p> <p>20 routine screening for those conditions as</p> <p>21 well, and then I am aware that there's more</p> <p>22 referral to specialists. So those things are</p> <p>23 all true.</p> <p>24 However, I'm also aware that</p> <p>25 using standardized methodology and different</p>
<p style="text-align: right;">Page 115</p> <p>1 surveillance methods in a prospective fashion</p> <p>2 that occur at frequent intervals. So that's</p> <p>3 an approach, for example, that the CDC uses.</p> <p>4 They use standardized methodology at regular</p> <p>5 intervals with valid, reliable outcome</p> <p>6 measures.</p> <p>7 In addition to that, you can</p> <p>8 look at sort of medical diagnosis rates from</p> <p>9 electronic medical records, things like that.</p> <p>10 So you're having a standardized methodology</p> <p>11 applied at regular intervals over time in</p> <p>12 order to determine, you know, prevalence</p> <p>13 rates.</p> <p>14 There you see, you know, that</p> <p>15 the prevalence rates are increasing using the</p> <p>16 same assessment measures and the same</p> <p>17 methodology in a prospective fashion at</p> <p>18 regular intervals, and that you get the --</p> <p>19 you get similar kinds of rates, or you get</p> <p>20 similar increases in rates, with different</p> <p>21 methods, whether you're looking at electronic</p> <p>22 medical records and clinician diagnoses or</p> <p>23 whether you're using other sampling kind of</p> <p>24 techniques.</p> <p>25 Q. Okay. I appreciate that,</p>	<p style="text-align: right;">Page 117</p> <p>1 approaches, you know, the rates continue to</p> <p>2 increase. And so I believe that while some</p> <p>3 of those factors may contribute to some</p> <p>4 extent, there's still a significant increase</p> <p>5 even when you control for all of those other</p> <p>6 kind of factors.</p> <p>7 Q. Dr. Hollander, do you believe</p> <p>8 the same thing for ADHD? Because you were</p> <p>9 asked -- answering about autism.</p> <p>10 A. I was answering for autism.</p> <p>11 And I think with regards to</p> <p>12 ASD, you know, the results are a little bit</p> <p>13 different.</p> <p>14 Q. ADHD. I don't mean to</p> <p>15 interrupt you, but you said ASD.</p> <p>16 A. I'm sorry. I apologize.</p> <p>17 Q. We're talking ADHD.</p> <p>18 A. Yeah. Right.</p> <p>19 Q. I just want to save you from</p> <p>20 having to repeat it.</p> <p>21 A. No. Well, yeah. I do believe</p> <p>22 that the rates for ADHD have increased over</p> <p>23 time, not as dramatically, but there has been</p> <p>24 an increase, and that I -- that represents an</p> <p>25 increase in the true prevalence and --</p>

<p style="text-align: right;">Page 118</p> <p>1 although there could be other factors that, 2 you know, contribute to the diagnosis. 3 Also, the same answer. Using 4 standardized methods and different 5 approaches, there's still a significant 6 increase in rates over time. 7 The time -- the time span is a 8 little bit different. So the time spans that 9 are kind of measured, in ASD you have a nice 10 period of 20 years where you can sort of 11 measure that using standardized methodology. 12 Here, the time intervals are a 13 little bit different, but the finding is 14 similar, that there's an increased rate, even 15 if you account for awareness and screening 16 and diagnostic changes and, you know, other 17 kinds of factors like services and things 18 like that. 19 Q. Okay. Dr. Hollander, let's go 20 through some of those factors. 21 So with respect to ADHD, the 22 diagnostic criteria did, in fact, expand 23 quite a bit, right? 24 A. Well, there were some changes, 25 for example, with regards to age of onset.</p>	<p style="text-align: right;">Page 120</p> <p>1 artificial cutoff where it demands that it's 2 identified by a certain age, then you may be 3 minimizing the illness. 4 I mean, the second issue is 5 gender issue. So ADHD is much less likely to 6 be picked up in women, partly because women 7 have less, you know, disruptive behavior, 8 temper tantrums, irritability, hyperactivity. 9 And therefore, again, you know, there's an 10 underrepresentation. 11 And so I think it's a step in 12 the right direction by including a different 13 age cutoff because it gives you a more 14 accurate representation. 15 But nevertheless, you're right, 16 there was a change in that diagnostic 17 criteria. 18 Q. And that increase -- and that 19 resulted in a significant increase in the 20 number of diagnoses in the United States, 21 correct? 22 A. It did identify many 23 individuals who hadn't been diagnosed prior 24 to that because of that cutoff. 25 Q. Right.</p>
<p style="text-align: right;">Page 119</p> <p>1 Q. 7 versus 12, right? 2 A. Correct. 3 Q. Okay. So you went from having 4 diagnoses for people who had symptoms before 5 7 to including five more years, anybody who 6 had symptoms before 12, right? 7 A. That's true. That is a change. 8 You know, part of the reason 9 for that is that there was a significant 10 underdiagnosis of individuals with adult 11 ADHD. And so it didn't really represent the 12 true prevalence of adult ADHD because there 13 was this artificial cutoff. And when you 14 expand the, you know, onset of presentation, 15 you may get a more accurate presentation. 16 And that's particularly true 17 for -- so one of the issues is people have 18 the inattentive, you know, subtype. There's 19 a large, I guess, misidentification. Those 20 individuals may not be -- if you're not 21 exploding or having temper tantrums, you're 22 not impulsive, you're not hyperactive, you're 23 less likely to be picked up, right? So it 24 may present in adulthood. 25 And then if you have an</p>	<p style="text-align: right;">Page 121</p> <p>1 And so you would agree with me 2 that that change, the change from 7 to 12, 3 greatly increased the diagnoses of ADHD in 4 the United States, correct? 5 MR. DOVEL: Objection. Form. 6 THE WITNESS: Well, I would say 7 that, you know, it's certainly 8 possible that that could be a factor 9 that could alter, you know, diagnostic 10 rates. 11 However, you know, one of the 12 things that I would say, though, in 13 the ADHD is at the time -- so the -- 14 2013 was when DSM-5 was published, 15 right? And that the surveillance 16 techniques in ADHD were often for 17 relatively time -- shorter time 18 periods. So you could -- I mean, you 19 could specifically control for that by 20 looking at, you know, rates. Rates 21 after 2013, you know, the criteria 22 would be the same. 23 QUESTIONS BY MR. MURDICA: 24 Q. What's the average age, 25 Dr. Hollander, of the diagnosis of ADHD in</p>

<p style="text-align: right;">Page 122</p> <p>1 the United States?</p> <p>2 A. Well, you're raising a good</p> <p>3 point in that, you know, the longer the</p> <p>4 follow-up, the higher the number of</p> <p>5 individuals that you're going to be picking</p> <p>6 them up.</p> <p>7 I think that patients -- I</p> <p>8 guess it varies. Again, the hyperactive,</p> <p>9 impulsive individuals are going to be</p> <p>10 diagnosed much earlier, and the inattentive</p> <p>11 subgroup are going to be diagnosed much</p> <p>12 later. The girls are going to be diagnosed</p> <p>13 later. So that there are different factors</p> <p>14 that influence age of onset.</p> <p>15 Q. Yeah.</p> <p>16 And do you know the average age</p> <p>17 of diagnosis, Doctor, in the US?</p> <p>18 A. I think often, you know, the</p> <p>19 diagnosis can be made, you know, by around</p> <p>20 age 7, but there are many -- you know, many</p> <p>21 people who don't present until after -- until</p> <p>22 12. I mean, that's why the diagnostic</p> <p>23 criteria have changed.</p> <p>24 Q. What's the average age of</p> <p>25 diagnosis of autism or ASD in the United</p>	<p style="text-align: right;">Page 124</p> <p>1 on the cohort, the racial and ethnic group.</p> <p>2 And so there are a lot of different factors</p> <p>3 that influence it.</p> <p>4 I could say that kids are often</p> <p>5 diagnosed -- you know, truthfully, the --</p> <p>6 well, you have two different factors</p> <p>7 competing. One is more screening and early</p> <p>8 diagnosis, but then the idea that -- you</p> <p>9 know, you're picking up more individuals with</p> <p>10 milder forms, so it's working in two</p> <p>11 different directions. But it may be</p> <p>12 around -- and it -- definitely there are big</p> <p>13 factors in terms of racial and ethnic and</p> <p>14 socioeconomic factors.</p> <p>15 I would say maybe like around</p> <p>16 age 5, but it really varies. Some people are</p> <p>17 being picked up at 18 months, and some people</p> <p>18 are picked up at adulthood.</p> <p>19 Q. Right. And I understand all of</p> <p>20 the qualifiers, Dr. Hollander.</p> <p>21 But in general, you would --</p> <p>22 you would testify here that if you factor in</p> <p>23 everybody who has a diagnosis, the age of</p> <p>24 diagnosis on average for ADHD across all the</p> <p>25 different populations is about age 7, and for</p>
<p style="text-align: right;">Page 123</p> <p>1 States?</p> <p>2 A. The age of onset with autism,</p> <p>3 again, really varies based on the</p> <p>4 presentation. So you've got kids who are,</p> <p>5 you know, aggressive and having temper</p> <p>6 tantrums. They're going to be diagnosed at a</p> <p>7 much earlier age.</p> <p>8 Girls are going to be diagnosed</p> <p>9 at a much later age.</p> <p>10 Those individuals with high IQ,</p> <p>11 those would good verbal ability, are going to</p> <p>12 be diagnosed at a much later age.</p> <p>13 So the -- and now we're finding</p> <p>14 that, you know, more and more people who are</p> <p>15 higher-functioning and who have good verbal</p> <p>16 skills are really not diagnosed until</p> <p>17 adulthood, actually.</p> <p>18 Q. And --</p> <p>19 A. So it depends on the -- it</p> <p>20 depends on the phenotypic presentation.</p> <p>21 Q. I understand that,</p> <p>22 Dr. Hollander. And all I'm asking is, do you</p> <p>23 know the statistic in the United States of</p> <p>24 the average age of diagnosis of autism?</p> <p>25 A. Well, then, again, it depends</p>	<p style="text-align: right;">Page 125</p> <p>1 autism across all the different populations</p> <p>2 and given all those caveats is around 5.</p> <p>3 Fair?</p> <p>4 MR. DOVEL: Objection. Form.</p> <p>5 THE WITNESS: I would say that</p> <p>6 those estimates are roughly</p> <p>7 appropriate. And I'll also say that</p> <p>8 the age of onset of ASD tends to be</p> <p>9 before the onset of ADHD.</p> <p>10 But I would also say there are</p> <p>11 so many different -- it really depends</p> <p>12 on the cohort that you're measuring it</p> <p>13 in because it can vary.</p> <p>14 QUESTIONS BY MR. MURDICA:</p> <p>15 Q. And, Dr. Hollander, one of the</p> <p>16 other reasons that the diagnoses -- the</p> <p>17 number of diagnoses are increasing in the</p> <p>18 United States, I think you mentioned earlier,</p> <p>19 but more awareness by medical providers to</p> <p>20 look for these symptoms in women, right? In</p> <p>21 female children?</p> <p>22 A. Well, I agree, without a doubt,</p> <p>23 there's been an underdiagnosis in women for a</p> <p>24 number of different reasons. So, you know,</p> <p>25 in -- so in ASD, there's a 4 to 1 ratio.</p>

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1 Maybe that's not really an accurate ratio,
 2 and maybe -- and some have suggested a more
 3 recent kind of approach is that the ratio
 4 could be lower than that.
 5 And so I -- as I mentioned
 6 before, you know, women tend to get
 7 underdiagnosed. And in particular, you know,
 8 women who have verbal ability and are not
 9 exploding, they're much less likely to be
 10 diagnosed, and they're much more likely, if
 11 they're going to be diagnosed, to be
 12 diagnosed at a later age.
 13 I can tell you that I have a
 14 lot of women in my practice who were not
 15 diagnosed until adulthood, actually, and they
 16 were given other diagnoses prior to that.
 17 Q. Dr. Hollander, with respect to
 18 ADHD, there used to be a similar large
 19 imbalance between the sexes, and now it's
 20 almost close to parity, isn't it -- is it
 21 not?
 22 MR. DOVEL: Objection. Form.
 23 THE WITNESS: Well, I would
 24 agree that, you know, there was a
 25 higher male-to-female ratio, and I

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1 would agree that over time that that
 2 ratio is narrowing as more women,
 3 particularly with those with the
 4 inattentive subtype, are being picked
 5 up.
 6 QUESTIONS BY MR. MURDICA:
 7 Q. And you said earlier in one of
 8 your answers, I believe, that another reason
 9 for increasing diagnoses are the availability
 10 of services, right?
 11 A. That's correct.
 12 Q. Okay. In 2004, the IDEA was
 13 passed which had a -- it was a significant
 14 benefit for children with autism and ADHD
 15 diagnoses in school in terms of not being
 16 separated from classes and getting the same
 17 quality of education with their diagnosis,
 18 correct?
 19 A. Well, I would agree that there
 20 are different purposes or uses of a
 21 diagnosis. And I would agree, for example,
 22 in the case of autism that getting an autism
 23 diagnosis can be associated with the ability
 24 to obtain certain services, yeah.
 25 Q. Services, Doctor, that were not

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1 available 30 years ago, correct?
 2 MR. DOVEL: Objection. Form.
 3 THE WITNESS: Well, I mean, I
 4 would say that -- services that may
 5 not have been accessible. They may
 6 have been available, but people may
 7 not have had as much access to those
 8 services.
 9 QUESTIONS BY MR. MURDICA:
 10 Q. Okay.
 11 A. But things like, you know,
 12 behavioral therapies and occupational
 13 therapy, speech therapy, those were -- those
 14 were around for a long time, but having a
 15 diagnosis can impact the ability to get
 16 services.
 17 Q. And services have become more
 18 available through school districts with
 19 increased awareness over time, right?
 20 There's more services available
 21 with a diagnosis now than there was a decade
 22 ago; is that fair?
 23 A. Yeah, I would say that there
 24 are more services available now than 20 years
 25 ago.

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1 Q. Okay. And let's see if you can
 2 agree on some other things that a
 3 diagnosis -- that a diagnosis changes.
 4 If you get an ADHD diagnosis
 5 now, a student in school will get extra time
 6 on tests, right?
 7 A. That's true, you can get some
 8 accommodations with a diagnosis.
 9 Q. Right.
 10 And one accommodation is extra
 11 time on testing, right?
 12 A. That's correct.
 13 Q. One accommodation is extra time
 14 on standardized testing like the SAT, right?
 15 A. You may be able to get that,
 16 although there are a lot of hurdles that you
 17 have to go through in order to actually
 18 obtain that. But that's true.
 19 Q. Okay. In fact, you can
 20 actually get SSI with a diagnosis in some --
 21 in some cases, right?
 22 A. Well, you know, if you have a
 23 neurodevelopmental disorder and you're
 24 disabled, you can get benefits.
 25 Q. You can get private tutors from

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1 the school district with a diagnosis,
 2 correct?
 3 A. You can get services.
 4 Q. You can get individual
 5 education plans, IEPs?
 6 A. Yes, with a diagnosis.
 7 Q. Okay. Any other services you
 8 can think of?
 9 A. Well, there may be -- I mean,
 10 people definitely can benefit from executive
 11 function coaches, for example. There may be
 12 some socialization-type services that you can
 13 also get.
 14 Q. Are you familiar with IDEA, the
 15 congressional act?
 16 A. Yeah.
 17 Q. Okay. Are you familiar with
 18 the change in rate -- change in number of
 19 diagnoses following the passage of that act?
 20 A. I haven't looked at the timing
 21 and the impact of the timing on the slope of
 22 the rates.
 23 Q. In your report, you were only
 24 looking prior to about 1996, right? In terms
 25 of the change in diagnosis rates of autism?

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1 A. Well, in my report, for
 2 example, I also had a figure from my
 3 California ecological study that looked at
 4 rates over longer periods of time.
 5 Q. Okay. And I'm talking about
 6 the US diagnosis rate. The cutoff of what
 7 you looked at went to about the mid-'90s,
 8 right?
 9 A. I don't recall. Maybe you
 10 could -- if you're talking about a specific
 11 aspect in my report, you could point me to
 12 that --
 13 Q. Sure.
 14 A. -- and I can comment on that.
 15 Q. And we'll do that after lunch.
 16 A. Okay.
 17 Q. Do you know --
 18 A. But I -- but I -- but I did
 19 cite in my report studies in the state of
 20 California that looked at the rates over
 21 really extended time periods.
 22 Q. Okay. Do you know nationally
 23 what -- do you know what year IDEA was
 24 passed?
 25 A. Not off the top of my head.

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1 Maybe you could inform me.
 2 Q. 2004.
 3 Do you know what happened to
 4 diagnosis rates after 2004?
 5 A. We could take a look at some
 6 figures.
 7 Q. Sitting here today, you don't
 8 know if it changed dramatically, right?
 9 A. I haven't reviewed figures.
 10 I'd be interested in looking at those figures
 11 and then looking at 2004 to see how that
 12 particular -- because there are various -- so
 13 there are a lot of different things that have
 14 happened that may have some impact one way or
 15 another in terms of rates of these
 16 conditions.
 17 And I think you could point to
 18 a range of different -- so I would point -- I
 19 think one important time period would be the
 20 rate that doctors put warnings on ibuprofen
 21 with regards to maternal usage and the
 22 timeline of those different warnings which
 23 influenced, you know, the exposure rates, and
 24 then look at those changes in the exposure
 25 rates and then how they relate to outcome

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1 rates.
 2 Q. Right.
 3 A. So there are a lot of different
 4 things that you could look that could
 5 potentially have some influence on outcome
 6 rates.
 7 Q. One of the things you pointed
 8 to, Dr. Hollander, in your report were the
 9 Tylenol murders in 1982, right?
 10 A. Yeah.
 11 Q. And your theory is that the
 12 publicity around the Tylenol murders in
 13 Chicago in 1982 nationally caused pregnant
 14 women to stop using acetaminophen, correct?
 15 A. Well, yeah, I mean, the -- I
 16 guess the public awareness about, you know,
 17 that particular contamination or outcome
 18 influenced the usage, right? And that would
 19 be something to look at. So that would be
 20 something that would affect exposure. And
 21 then you want to see whether a change in
 22 exposure affected a change in outcome.
 23 Q. Right.
 24 So you would want to see,
 25 Dr. Hollander, if, following the Tylenol

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1 murders in 1982, if the autism diagnosis rate
 2 went down five years later at about the
 3 average time of autism diagnosis, correct?
 4 A. Well, five -- I mean, I would
 5 probably want to look at it in a broader
 6 range than just five years, to tell you the
 7 truth, because, again, people can present at
 8 different ages.
 9 Q. Right.
 10 But we're talking about
 11 averages, right? You're looking at
 12 statistics overall. You want to look at the
 13 average, correct?
 14 A. I guess you'd want to look at
 15 the mean and maybe the median, so there are
 16 different ways to look at it.
 17 Q. Okay. And if we were looking
 18 at whether the Tylenol murders had an impact
 19 on the ADHD diagnosis rate, we'd look a
 20 little further out, more like six or seven
 21 years, like you said, right, Doctor?
 22 MR. DOVEL: Objection. Form.
 23 THE WITNESS: Well, it would be
 24 the same caveat again because there
 25 are a lot of nuances in terms of

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1 presentation, and those nuances depend
 2 on the cohort that you're looking at.
 3 So...
 4 QUESTIONS BY MR. MURDICA:
 5 Q. Okay.
 6 A. But -- but there would be some
 7 time association, but it could be depending
 8 on what are the cohorts that you're measuring
 9 it in.
 10 Q. Doctor, on average, if we're
 11 looking at autism rates in 1984, we're really
 12 looking at births in 1979, 1980, correct?
 13 A. Well, that would be the case if
 14 we assume your average of five years and
 15 you're talking about ASD, right?
 16 Q. I'm talking about ASD, yeah.
 17 A. Okay.
 18 Q. If we're looking at autism
 19 diagnosis rates in 1984, we'd really be
 20 talking about children born in 1979, 1980, on
 21 average, correct?
 22 A. Again, but with the same, you
 23 know, caveats in terms of the average.
 24 Q. Okay. What do you know about
 25 the benefits offered to Cuban citizens for

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1 different neurodevelopmental diagnoses?
 2 A. I would imagine that the
 3 benefits in Cuba are not identical to the
 4 benefits offered in the United States.
 5 Q. Do you know anything about the
 6 benefits offered in Cuba?
 7 A. Well, I do know that, you know,
 8 Cuba is a Third World country, and so -- and,
 9 you know, a much poorer country with less
 10 access to various kinds of services.
 11 Q. Do you think there would be --
 12 do you know if there's any stigmas attached
 13 to having a diagnosis like autism in Cuba?
 14 A. You know, there's a good point
 15 because -- so then you have these two sort of
 16 competing issues, so stigma versus, you know,
 17 benefits, for example.
 18 Yeah, I do think that there are
 19 differences with regard to cultural factors
 20 and stigma.
 21 Q. And you haven't done any
 22 analysis on why and how autism is diagnosed
 23 or not diagnosed in Cuba, have you?
 24 A. You know, I've read things that
 25 allude to that. You know, I haven't studied

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1 it in detail, you know. It's clear that
 2 there's less services available, and so
 3 there's probably less screening and referral
 4 and access to different kinds of services.
 5 Q. Let me -- let me put this
 6 simply, Dr. Hollander.
 7 Is it really -- is
 8 Dr. Hollander really relying on diagnosis
 9 rates in Cuba to render your causation
 10 opinion here that acetaminophen can cause ASD
 11 and ADHD?
 12 A. No, I'm not relying on --
 13 Q. Okay.
 14 A. -- diagnosis rates in Cuba --
 15 Q. Okay.
 16 A. -- to support my opinions here.
 17 MR. MURDICA: When do you guys
 18 want to do lunch? I can take a break
 19 now or move to another area.
 20 MS. HEACOX: I think it's going
 21 to be delivered at 12:30, supposedly.
 22 MR. MURDICA: Okay.
 23 MR. DOVEL: So let's keep going
 24 until 12:30.
 25 MR. MURDICA: Let's keep going.

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1 QUESTIONS BY MR. MURDICA:
 2 Q. All right. After lunch we're
 3 going to mark your rebuttal report, but I'm
 4 going to ask you some questions about it now.
 5 We'll see if you can answer them without it.
 6 If not, we'll move on to something else.
 7 In your Bradford Hill analysis,
 8 one of the factors you looked at was
 9 temporality.
 10 Do you remember that?
 11 A. Yes, I do.
 12 Q. Okay. And temporality -- you
 13 ascribed, you say in the rebuttal report,
 14 that you put great significance on the
 15 satisfaction of that element in your
 16 analysis.
 17 Do you recall that?
 18 A. I do.
 19 Q. Okay. And the only thing
 20 required to satisfy temporality, according to
 21 the analysis in your report, is that the
 22 exposure occurred before the birth, right?
 23 A. Essentially, yes.
 24 Q. Okay. So Dr. Hollander, isn't
 25 that -- isn't that really a yes or no and not

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1 a great or limited significance?
 2 A. Well, look, if we're talking
 3 about exposure and outcome, and that's what
 4 we're talking about, and we're talking about
 5 maternal exposure, yeah. So then, yeah, the
 6 exposure has to occur during the maternal
 7 period.
 8 Q. Right.
 9 But it's not like there's
 10 anything unique about acetaminophen exposure
 11 compared to other exposure for this factor,
 12 for temporality, correct? Any exposure
 13 before the birth you're counting as
 14 satisfied, fair?
 15 A. Yes. I mean, there are all
 16 these nuances in terms of how you measure
 17 exposure. But, yes, with regards to just the
 18 issue of temporality, yeah, that the exposure
 19 had to occur during pregnancy.
 20 Q. One of the other things you say
 21 in considering your Bradford Hill analysis is
 22 that you're looking at results that were
 23 statistically significant, right?
 24 A. Yes.
 25 Q. Okay. And you know what

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1 statistical significance is, correct?
 2 A. Yes.
 3 Q. And statistical significance is
 4 important for you to identify a relation -- a
 5 causal relationship between an exposure and
 6 an outcome, right?
 7 A. Statistical significance is
 8 important as one of the overall factors in
 9 terms of how you determine, you know, the
 10 strength of the association between exposure
 11 and the outcome, but it's not the only
 12 factor.
 13 Q. Right.
 14 A. And so you'd want to look at
 15 confidence intervals, for example. You'd
 16 want to look at consistency of findings.
 17 You'd want to look at reproducibility or
 18 replication. But statistical significance is
 19 important.
 20 However, you know, you can
 21 still determine causation without statistical
 22 significance, but it's one important factor.
 23 But you'd also want to look at, you know,
 24 confidence intervals, and you'd want to look
 25 at consistency, and you'd want to look at

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1 replication, and you'd want to look at, you
 2 know, whether multiple different studies
 3 showed the same, you know, direction.
 4 So whether it's a positive
 5 association or whether it's a negative
 6 association, you look at all of that. You
 7 weight all the evidence, and then that can
 8 help to determine causation.
 9 Q. Dr. Hollander, isn't -- aren't
 10 the confidence intervals how you define
 11 statistical significance?
 12 A. The confidence intervals don't
 13 exactly map onto the p-value. So they're two
 14 different sort of measures of strength of
 15 association.
 16 Q. Okay. For a point estimate to
 17 be statistically significant, the confidence
 18 interval has to be entirely over 1, correct?
 19 A. Again, not necessarily. So,
 20 again, like when you're looking at the
 21 totality of the evidence, what you want to do
 22 is, yeah, you do want to look at the
 23 confidence intervals.
 24 However, you know, even if in
 25 an individual study the confidence interval

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1 may be below 1, you know, if it's a positive
 2 association that occurs over and over and
 3 over again, then it wouldn't be disqualifying
 4 or troubling to have an individual study
 5 where the confidence interval was below 1.
 6 Same thing as the p-value. I
 7 mean, you want the p-value to be less than
 8 .05. You'd want there to be a -- but you'd
 9 also want there to be, you know, a positive
 10 association that occurs over and over again
 11 in the same direction with replication. Then
 12 it may be that there are some studies that
 13 don't reach a p-value of .05, but -- so you
 14 want to look at the totality, really, in
 15 order to understand the association that
 16 informs causation.
 17 Q. Do you think you answered my
 18 question?
 19 A. I think so. I think the answer
 20 is, it depends. So you can -- you can have
 21 causation even if the p-value in some cases
 22 is greater than .05, and you can have
 23 causation even if you have some studies where
 24 the confidence interval is less than 1, yes.
 25 Q. Okay. My question was this.

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1 Let's try it one more time.
 2 For a point estimate to be
 3 statistically significant, the confidence
 4 interval has to be entirely over 1, correct?
 5 A. Generally that's the case.
 6 Q. Okay. And statistically that's
 7 the case, right? That's the very definition
 8 in statistics, correct?
 9 A. I would say that that -- that
 10 is generally the case for a single-point
 11 estimate.
 12 Q. And that was my only question.
 13 A. Okay.
 14 Q. All right. For a p-value to be
 15 important to you, does it need to be .05 or
 16 less?
 17 A. No.
 18 Q. Okay. What p-value matters to
 19 Dr. Hollander?
 20 A. Well, we also look at trends.
 21 So, you know, a trend can be -- even if the
 22 p-value is greater than .05, you may have a
 23 trend. It really depends on the sample size.
 24 So, for example, in preliminary
 25 studies, when you're trying to understand an

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1 association and you're trying to do a power
 2 analysis, you're looking at the effect size.
 3 The thing that's most important is the size
 4 of the effect and not the p-value.
 5 Q. Okay.
 6 A. And then you take that
 7 information, and then you can use that
 8 information to design studies of adequate
 9 sample size.
 10 So you can have a trend that's
 11 very important. You can establish an odds
 12 ratio or an effect size, and then you can
 13 utilize that information. That could be very
 14 valuable even if the p-value is greater than
 15 .05.
 16 Q. Is there a p-value that
 17 statisticians generally consider to be the
 18 target p-value to find an association?
 19 A. Well, there are some general
 20 assumptions, and then there are -- certainly
 21 there are some occasions where the
 22 association is very important. It gives you
 23 critical information, even if the p-value is
 24 greater than .05.
 25 Q. Yeah.

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1 And --
 2 A. So you want to -- again, like
 3 one example again is that if you have studies
 4 over and over again that show the same
 5 positive association, the same direction, the
 6 same trend, even if you have a p-value
 7 than -- that's less than -- that's greater
 8 than .05, then it -- then it provides very
 9 important information.
 10 You can still include that, for
 11 example, in meta-analyses. And then when you
 12 pull the data with a bigger sample size, then
 13 you -- so the P -- the p-value is simply
 14 influenced by the sample size, right? That's
 15 the nice thing about meta-analyses. You can
 16 pull the data that shows an effect and
 17 establish a much bigger sample size. Then
 18 that can give you a much stronger p-value.
 19 Q. Dr. Hollander, my question was
 20 this: Is there a p-value that statisticians
 21 generally consider to be the target p-value
 22 to find an association in a given study?
 23 A. Well, there's a general
 24 assumption that P equals less than .05 --
 25 Q. That's all I was asking.

<p>Page 146</p> <p>1 A. -- is a strong association. 2 But again, it all depends on the sample size. 3 So the p-value is influenced by the sample 4 size. 5 What you -- any information 6 that you gain from that determine -- is 7 determined by the design of the study. So if 8 the -- if the study has an insufficient 9 sample size, it may give you a p-value that's 10 greater than .05. And then you need to 11 interpret that with regards to interpreting 12 the study. 13 You say, well, all right, so 14 that particular study has a low sample size. 15 Let's see what happens if we pull the data 16 from different studies with a low sample 17 size, so all of a sudden we have a bigger 18 sample size. Then that's going to give you a 19 different p-value. 20 Q. You're talking about a 21 meta-analysis -- 22 A. That's an example. 23 Q. -- in that example, correct? 24 A. Yeah, that's an example of 25 that.</p>	<p>Page 148</p> <p>1 A. I attempted to evaluate the 2 data, understanding the design of the 3 different studies and controlling for various 4 forms of confounders or bias and using 5 standard methodology in order to interpret 6 that. 7 Q. You know what EB05 is, right? 8 A. Yes. 9 Q. And in fact, in another 10 litigation you did a disproportionality 11 analysis to determine causation, correct? 12 A. It's possible that I did that 13 analysis. 14 Q. And the EB05 is the important 15 part of the disproportionality analysis to 16 show the association, correct? 17 A. Well, no. I mean, I think 18 you -- there are different ways to -- there 19 are different types of analyses, and it 20 depends on the association that you're 21 looking at. 22 Q. Okay. Here, for acetaminophen 23 and ADHD and autism, did you do a 24 disproportionality analysis? 25 A. I don't believe that I did a</p>
<p>Page 147</p> <p>1 But you can pull data outside 2 of meta-analyses as well, so -- 3 Q. In a single analysis, in a 4 single study, is it accurate, based on what 5 you just said, that generally the target 6 p-value is something less than .05, 7 Dr. Hollander? 8 A. Well, I think my answer again 9 is usually in a single study, generally the 10 goal, if you want to disprove a null 11 hypothesis, is to obtain that. But the study 12 is only good -- it's only as good as the 13 design of the study, right? So that there 14 are various issues in terms of the study 15 design that you need to evaluate in order to 16 judge the value of a particular study. 17 So, you know, again, you know, 18 for pilot studies, we don't even pay 19 attention to the p-value. We're much more 20 interested in the effect size rather than the 21 p-value. And then we use that strength of 22 the association based on the effect size then 23 to power additional studies, for example. 24 Q. Dr. Hollander, did you attempt 25 to do a disproportionality analysis here?</p>	<p>Page 149</p> <p>1 disproportionality analysis -- 2 Q. Why not? 3 A. -- here. 4 Q. Why not? 5 A. It depends on the -- so, for 6 example, each -- there are significant 7 differences in each individual case in terms 8 of the compound, in terms of the reporting 9 and the data available in order to do that 10 type. 11 One issue here is that 12 acetaminophen has been on the market for a 13 long time, and it's an over-the-counter 14 medicine as opposed to a prescription 15 medication. So that there may be data 16 available from prescription medications where 17 you can do certain analyses. When you're 18 looking at effects on over-the-counter 19 medication, you may not have access to all 20 that kind of information to be able to do all 21 those analyses. 22 Q. Did you ask for that 23 information here? 24 A. You know, the problem, I guess, 25 here is that the vast majority of individuals</p>

<p style="text-align: right;">Page 150</p> <p>1 who were taking acetaminophen are not taking</p> <p>2 it as part of a prescription product.</p> <p>3 Q. Did you ask for the</p> <p>4 information, if it's available?</p> <p>5 A. I didn't ask for the</p> <p>6 information, if it's available. However,</p> <p>7 unfortunately, I think it would be less</p> <p>8 relevant because the majority of the exposure</p> <p>9 is occurring with over-the-counter usage.</p> <p>10 MR. MURDICA: Okay. It's</p> <p>11 12:30. Do you want to take our lunch</p> <p>12 break?</p> <p>13 MR. DOVEL: Let's go off the</p> <p>14 record and talk about that.</p> <p>15 VIDEOGRAPHER: The time right</p> <p>16 now is 12:30 p.m. We are off the</p> <p>17 record.</p> <p>18 (Off the record at 12:30 p.m.)</p> <p>19 VIDEOGRAPHER: The time right</p> <p>20 now is 1:04 p.m. We are back on the</p> <p>21 record.</p> <p>22 QUESTIONS BY MR. MURDICA:</p> <p>23 Q. Dr. Hollander, welcome back.</p> <p>24 A. Welcome back.</p> <p>25 Q. Are you ready to proceed?</p>	<p style="text-align: right;">Page 152</p> <p>1 Do you recognize that as your bio?</p> <p>2 MR. DOVEL: Objection. Form.</p> <p>3 THE WITNESS: Well, I recognize</p> <p>4 that this is a description of me</p> <p>5 that's on that website.</p> <p>6 QUESTIONS BY MR. MURDICA:</p> <p>7 Q. All right. And this is your</p> <p>8 website, right?</p> <p>9 A. This is one of my websites,</p> <p>10 yes.</p> <p>11 Q. Do you see anything about ADHD</p> <p>12 on here?</p> <p>13 A. Well, I see information here</p> <p>14 about impulsivity and aggression and other</p> <p>15 specific impulse control disorders like</p> <p>16 gambling. So that ADHD plays a fundamental</p> <p>17 role in all of the impulse control disorders</p> <p>18 and impulsivity and aggression.</p> <p>19 Q. Okay. Dr. Hollander, your bio</p> <p>20 on Spectrum Neurosciences doesn't say</p> <p>21 attention-deficit/hyperactivity disorder,</p> <p>22 correct?</p> <p>23 A. Well, as I recall on the</p> <p>24 website, yes. You know, there is a</p> <p>25 description of our expertise with regards to</p>
<p style="text-align: right;">Page 151</p> <p>1 A. Yes, I am.</p> <p>2 Q. Okay. Earlier this morning, I</p> <p>3 asked you about your website for Spectrum</p> <p>4 Neurosciences.</p> <p>5 Do you recall those questions?</p> <p>6 A. Yes.</p> <p>7 Q. Okay. And I asked if we</p> <p>8 looked, if it would say anything about you</p> <p>9 and ADHD.</p> <p>10 Do you recall that?</p> <p>11 A. Yes.</p> <p>12 Q. And you said it would, right?</p> <p>13 A. Yes.</p> <p>14 Q. Okay. Do you hold yourself out</p> <p>15 as an expert in ADHD?</p> <p>16 A. Yes.</p> <p>17 Q. Okay. And have you diagnosed</p> <p>18 causes of ADHD in your patients?</p> <p>19 A. Yes.</p> <p>20 (Hollander Exhibit 51 marked</p> <p>21 for identification.)</p> <p>22 QUESTIONS BY MR. MURDICA:</p> <p>23 Q. I'm just going to mark this as</p> <p>24 51.</p> <p>25 Dr. Hollander, do you -- sorry.</p>	<p style="text-align: right;">Page 153</p> <p>1 attention-deficit/hyperactivity disorder.</p> <p>2 Q. Yeah, and I'm asking</p> <p>3 specifically about Exhibit 51 in front of</p> <p>4 you --</p> <p>5 A. Right.</p> <p>6 Q. -- your bio on your website.</p> <p>7 We can look and look and look,</p> <p>8 but we're not going to see ADHD in this text,</p> <p>9 correct?</p> <p>10 A. No, I see -- I see we're</p> <p>11 talking about issues around impulsivity,</p> <p>12 which are fundamentally tied to ADHD. And I</p> <p>13 recall that there's a good description,</p> <p>14 actually, of ADHD and our overall services</p> <p>15 and what we focus on on that particular</p> <p>16 website, but I don't see ADHD listed on this</p> <p>17 particular bio.</p> <p>18 Q. Dr. Hollander, what -- you</p> <p>19 mentioned that this is just one of several</p> <p>20 websites.</p> <p>21 What other websites do you</p> <p>22 host?</p> <p>23 A. Well, we also have a website</p> <p>24 for the autism/obsessive compulsive spectrum</p> <p>25 disorders program at Albert Einstein College</p>

<p style="text-align: right;">Page 154</p> <p>1 of Medicine and the Montefiore Medical 2 Center, and also the fellowship program as 3 well on autism and obsessive compulsive 4 spectrum disorders on the Einstein and 5 Montefiore website. 6 And then there's also a website 7 on the Spectrum Neuroscience Research 8 Foundation. 9 Q. Okay. And you just mentioned 10 two websites on autism and OCD, correct? 11 A. I mentioned websites on the 12 autism and OCD spectrum program. 13 Q. Okay. What would you consider 14 your main website, Dr. Hollander? 15 MR. DOVEL: Objection. Form. 16 THE WITNESS: Well, I guess we 17 have those two different websites. 18 There's a research-related website, 19 and there's a clinical website. 20 QUESTIONS BY MR. MURDICA: 21 Q. Do you hold yourself out as a 22 researcher in attention-deficit/hyperactivity 23 disorder? 24 A. Well, I -- I'm an expert in 25 impulse control disorders and impulsivity,</p>	<p style="text-align: right;">Page 156</p> <p>1 which is fundamentally related to 2 ADHD. 3 QUESTIONS BY MR. MURDICA: 4 Q. Your prior testimony in 5 litigation for plaintiffs has been in 6 litigation over impulsivity like compulsive 7 gambling, correct? 8 A. Yes, I have offered opinions 9 and testimony around pathological gambling 10 and other impulse control disorders. 11 Q. Right. 12 And if we looked -- if we 13 looked at all your prior testimony, we 14 wouldn't see any on ADHD, correct? 15 A. You know, again, there's a -- 16 there's a -- so impulsivity is one of the 17 domains within ADHD, and ADHD is 18 fundamentally related to impulse control 19 disorders. 20 Q. So have you held yourself out 21 to another court before this one as an expert 22 in ADHD? 23 A. Well, I've held myself out as 24 an expert in impulsivity and in impulse 25 control disorders associated with ADHD.</p>
<p style="text-align: right;">Page 155</p> <p>1 and that the ADHD and the mechanisms involved 2 in ADHD are fundamental for impulsivity, 3 impulse control disorders and aggression. 4 Q. Is impulse control a diagnostic 5 criteria of ADHD? 6 A. Well, yes, it's one of the 7 domains within ADHD. So there's the 8 inattention domain. There's the 9 hyperactivity impulsivity domain, yes. So, 10 yes, the impulsivity is one of the domains of 11 ADHD. 12 Q. Okay. So back to my original 13 question. 14 You, Dr. Hollander, hold 15 yourself out to the world as an expert in 16 ADHD, correct? 17 MR. DOVEL: Objection. Form. 18 THE WITNESS: Yes, I'm an 19 expert in ADHD and in 20 neurodevelopmental disorders. 21 I treat, you know, a large 22 number of children, adolescents and 23 adults with ADHD. 24 I've gotten grants, federal and 25 nonfederal grants, on impulsivity,</p>	<p style="text-align: right;">Page 157</p> <p>1 Q. So any symptom of ADHD you're 2 considering is your expertise in ADHD? 3 That's how you get there? 4 A. Maybe you could repeat the 5 question -- 6 Q. Sure. 7 A. -- because I don't quite -- 8 Q. You're saying that -- we'll 9 take, for example, Abilify. You testified 10 about compulsive gambling, right? 11 A. I testified about compulsive 12 gambling and other impulse control disorders 13 as well. 14 Q. You did not -- we can look at 15 the transcript. We'd never see the words 16 "ADHD," right? 17 A. I don't think that that's 18 accurate because I do think that I -- in 19 discussing impulse control disorders, I would 20 have mentioned also the association with 21 ADHD. 22 Q. To the best of your 23 recollection, did you render opinions in 24 Abilify or Mirapex regarding 25 attention-deficit/hyperactivity disorder?</p>

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1 A. No. In Abilify and Mirapex, I
 2 rendered opinions with regards to
 3 impulsivity.
 4 Q. Okay. And the grants that
 5 you've gotten for obsessive control disorder,
 6 if we looked at the grants themselves, they
 7 weren't grants for ADHD specifically,
 8 correct? They were for OCD?
 9 A. I've also had grants for
 10 impulse control disorders such as
 11 pathological gambling.
 12 So I would say that I have made
 13 important contributions as it relates to both
 14 compulsivity and impulsivity, and I would say
 15 that I'm an expert as it relates to both
 16 compulsivity and impulsivity.
 17 Q. Okay. Do you remember my
 18 question?
 19 A. Well, it had to do with ADHD.
 20 Q. Yes.
 21 A. Perhaps you could read the last
 22 question again.
 23 Q. Sure.
 24 The grants you've gotten for
 25 obsessive -- OCD, if we look at the grants

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1 themselves, they weren't grants for ADHD
 2 specifically, correct?
 3 A. Well, the grants for obsessive
 4 compulsive disorder weren't for ADHD, and the
 5 grants for impulse control disorders weren't
 6 for ADHD.
 7 Q. Okay.
 8 A. They were for compulsive
 9 disorders or impulsive disorders.
 10 (Hollander Exhibit 52 marked
 11 for identification.)
 12 QUESTIONS BY MR. MURDICA:
 13 Q. All right. Let's mark your --
 14 I saw -- the questions I was asking you
 15 earlier, you had your rebuttal report in
 16 front of you. We're going to mark it. We're
 17 going to mark a copy. You can use whichever
 18 copy you want.
 19 A. I'm fine with my copy.
 20 Q. Okay. We'll just take it here.
 21 Okay. Dr. Hollander, you have
 22 in front of you what's been marked as
 23 Exhibit 52, which is your rebuttal report.
 24 Do you recognize that?
 25 A. Yes, I do.

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1 Q. Now, the version you're using
 2 is a version you brought with you that has
 3 your notes on it, right?
 4 A. Yes, that has my underlines on
 5 it.
 6 Q. Okay. All right. So one of
 7 the things you do in here in conducting your
 8 Bradford Hill is you reference Dr. Baccarelli
 9 several times as your reliance for this
 10 analysis, right?
 11 A. That's correct.
 12 Q. Okay. When did you first see
 13 Dr. Baccarelli's report?
 14 A. I believe I reviewed his report
 15 prior to my discussion with him.
 16 Q. And when was your discussion
 17 with him?
 18 A. My discussion with him was
 19 prior to issuing my initial amended report.
 20 Q. And by that you mean your first
 21 substantive report?
 22 A. That's correct.
 23 Q. Okay. And in relying on
 24 Dr. Baccarelli, are you deferring to
 25 Dr. Baccarelli, or are you saying this is an

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1 analysis that you, Dr. Hollander, are
 2 presenting to stand on its own?
 3 MR. DOVEL: Objection. Form.
 4 THE WITNESS: Well, I've
 5 reviewed his report in detail. I
 6 agree with the conclusions of his
 7 report, I utilize his report as
 8 background in preparing my report, and
 9 then I offer my opinions in my report.
 10 QUESTIONS BY MR. MURDICA:
 11 Q. All right. So, Dr. Hollander,
 12 you don't need Dr. Baccarelli's report to
 13 render the opinions in Exhibit 52, correct?
 14 MR. DOVEL: Objection. Form.
 15 THE WITNESS: Well, I'm --
 16 Dr. Baccarelli did a comprehensive
 17 review of all of the available
 18 literature. He did a comprehensive
 19 weighting of each of the different
 20 articles and then used the specific
 21 methodology, including his navigation
 22 guide.
 23 I reviewed, you know, his
 24 writing, and I reviewed his use of the
 25 navigation guide. I concur with the

<p style="text-align: right;">Page 162</p> <p>1 work that he's done, and I rely on the</p> <p>2 information in his report to support</p> <p>3 my opinions that are offered in my</p> <p>4 report.</p> <p>5 QUESTIONS BY MR. MURDICA:</p> <p>6 Q. Dr. Hollander, are you relying</p> <p>7 on Dr. Baccarelli's conclusions to support</p> <p>8 your opinion here?</p> <p>9 A. I'm relying on Dr. Baccarelli's</p> <p>10 report, and I'm relying on his weighting of</p> <p>11 each of the individual studies. That's in</p> <p>12 concordance -- so that is supportive of my</p> <p>13 opinions that are offered in my report.</p> <p>14 Q. So if Dr. Baccarelli's got it</p> <p>15 wrong, then you relied on him, and your</p> <p>16 report would not be accurate, correct?</p> <p>17 A. No, I wouldn't agree with that,</p> <p>18 because I did my own independent Bradford</p> <p>19 Hill analysis, which is the standard method</p> <p>20 to weight the information, you know, in order</p> <p>21 to render my opinion.</p> <p>22 Q. Okay. So this is what I'm</p> <p>23 trying to get straight, Dr. Hollander.</p> <p>24 Do you need Dr. Baccarelli to</p> <p>25 offer your opinions to the Court here or not?</p>	<p style="text-align: right;">Page 164</p> <p>1 Q. Yep.</p> <p>2 If you turn to page 8 on the</p> <p>3 bottom.</p> <p>4 A. Yeah.</p> <p>5 Q. Do you see you have a part F,</p> <p>6 temporality?</p> <p>7 A. Yeah.</p> <p>8 Q. Okay. Do you see --</p> <p>9 A. Oh, yes.</p> <p>10 Q. -- "I ascribe great weight to</p> <p>11 the element of temporality"?</p> <p>12 A. Yes, I see it.</p> <p>13 Q. Okay. And this is what we</p> <p>14 talked about before. It's really a yes or no</p> <p>15 whether the exposure came before the outcome,</p> <p>16 right?</p> <p>17 A. Yes.</p> <p>18 Q. So why did you ascribe it great</p> <p>19 weight?</p> <p>20 A. Well, because if the exposure</p> <p>21 causes the outcome, then the exposure needs</p> <p>22 to precede the outcome.</p> <p>23 Q. Right.</p> <p>24 And isn't that a yes or no</p> <p>25 question --</p>
<p style="text-align: right;">Page 163</p> <p>1 MR. DOVEL: Objection. Form.</p> <p>2 THE WITNESS: No. I relied on</p> <p>3 the information in the methods in</p> <p>4 Dr. Baccarelli's report, but that my</p> <p>5 report stands on its own in that I</p> <p>6 conducted my own Bradford Hill</p> <p>7 analysis of causation, and I offer my</p> <p>8 own opinion.</p> <p>9 QUESTIONS BY MR. MURDICA:</p> <p>10 Q. Okay. So while you mentioned</p> <p>11 Dr. Baccarelli several times here, these</p> <p>12 opinions in here are yours, correct?</p> <p>13 A. That's correct.</p> <p>14 Q. Okay. Okay. If we turn to</p> <p>15 page 8.</p> <p>16 Do you recall before lunch I</p> <p>17 was asking you about temporality?</p> <p>18 A. Yes.</p> <p>19 Q. And do you see on page 8 you</p> <p>20 have your temporality section, and you say</p> <p>21 you "ascribe great weight to the element of</p> <p>22 temporality"?</p> <p>23 Are you on page 8?</p> <p>24 A. Let's see. I'm looking at a</p> <p>25 section that I have on temporality here.</p>	<p style="text-align: right;">Page 165</p> <p>1 A. Yeah.</p> <p>2 Q. -- whether the exposure</p> <p>3 precedes the outcome?</p> <p>4 A. Yes.</p> <p>5 Q. Okay. So why would you give a</p> <p>6 yes or no great weight?</p> <p>7 A. Because it would be hard to</p> <p>8 meet causation under a Bradford Hill analysis</p> <p>9 if the exposure did not precede the outcome.</p> <p>10 Q. Okay. So on the next page, on</p> <p>11 experiment, you ascribe lesser weight to</p> <p>12 experiment, correct?</p> <p>13 A. That's right.</p> <p>14 Q. That was not a yes or no</p> <p>15 question, right?</p> <p>16 A. Well, you know, as I mention</p> <p>17 here, it's harder to ethically conduct</p> <p>18 randomized experiments in humans with regard</p> <p>19 to, you know, prenatal acetaminophen</p> <p>20 exposure, and so you need to look to other</p> <p>21 areas such as animal models as well.</p> <p>22 Q. Right.</p> <p>23 But there is human data on</p> <p>24 acetaminophen exposure during pregnancy,</p> <p>25 right?</p>

<p style="text-align: right;">Page 166</p> <p>1 A. Well, yes. There's</p> <p>2 epidemiology data.</p> <p>3 Q. Okay. So your justification</p> <p>4 for ascribing lesser weight here is</p> <p>5 essentially that there isn't randomized</p> <p>6 clinical trials?</p> <p>7 A. Right. For ethical reasons, it</p> <p>8 would be impossible, really, to do those kind</p> <p>9 of randomized clinical trials, for example,</p> <p>10 comparing exposure to acetaminophen versus</p> <p>11 exposure to ibuprofen, for example, in</p> <p>12 pregnant women, and then follow them up and</p> <p>13 look at the relationship between exposure and</p> <p>14 outcome --</p> <p>15 Q. You --</p> <p>16 A. -- because of ethical issues.</p> <p>17 Q. You know, don't you,</p> <p>18 Dr. Hollander, that there are prospective,</p> <p>19 double-blinded pregnancy registries, right,</p> <p>20 for this reason?</p> <p>21 A. Yes.</p> <p>22 Although getting back to your</p> <p>23 earlier question about EB05, for example,</p> <p>24 it's more challenging when there's a long</p> <p>25 time lag, and it's more challenging when</p>	<p style="text-align: right;">Page 168</p> <p>1 You know what double-blind</p> <p>2 means?</p> <p>3 A. I do know what double-blind</p> <p>4 means.</p> <p>5 The information is collected</p> <p>6 prospectively during pregnancy, and the</p> <p>7 outcome measures are collected independent of</p> <p>8 those measures. But I guess the subjects are</p> <p>9 aware of whether or not -- you know, so</p> <p>10 they're not taking a blinded -- they're not</p> <p>11 taking a blinded medication. And it's true,</p> <p>12 you're right. I mean, that's the issue about</p> <p>13 randomized, controlled trials. You can't</p> <p>14 give people either acetaminophen or, let's</p> <p>15 say, placebo to deal with their pain or their</p> <p>16 fever and then follow them up. That would be</p> <p>17 a blinded kind of a trial.</p> <p>18 Q. Right.</p> <p>19 And you've done those before,</p> <p>20 right?</p> <p>21 A. I haven't done them with</p> <p>22 regards to maternal exposure, but I do them</p> <p>23 all the time in terms of looking at efficacy</p> <p>24 and safety with different medications.</p> <p>25 Q. For example, treating autism</p>
<p style="text-align: right;">Page 167</p> <p>1 medicines aren't prescription but over the</p> <p>2 counter in terms of being able to get that</p> <p>3 kind of data.</p> <p>4 Q. Well, if it's a prospective</p> <p>5 pregnancy registry that's blinded, it's</p> <p>6 administered by researchers, so they have</p> <p>7 that data, correct?</p> <p>8 A. Well, I mean, that's the whole</p> <p>9 point of cohort studies, right? You want to</p> <p>10 collect that data prospectively with regards</p> <p>11 to exposure, and then you want to follow up</p> <p>12 the individuals, and then you want to figure</p> <p>13 out what the hazard ratios are to determine</p> <p>14 the relationship between exposure and</p> <p>15 outcome.</p> <p>16 Q. Right.</p> <p>17 And those aren't</p> <p>18 double-blinded, correct?</p> <p>19 A. They're not, you know,</p> <p>20 randomized, controlled trials contrasting</p> <p>21 acetaminophen to ibuprofen, for example.</p> <p>22 Q. Wasn't my question.</p> <p>23 They're not -- those registries</p> <p>24 that you're talking about are not</p> <p>25 double-blind, correct?</p>	<p style="text-align: right;">Page 169</p> <p>1 with marijuana, right?</p> <p>2 A. I have not conducted an autism</p> <p>3 trial with marijuana. That would be an</p> <p>4 incorrect statement.</p> <p>5 Q. Okay. Are you sure?</p> <p>6 A. Yes. I've conducted a trial</p> <p>7 with compounds derived from the cannabis</p> <p>8 plant, which is cannabidiol, which is not</p> <p>9 marijuana. It's not medical marijuana, no.</p> <p>10 It's extracting a compound from the plant and</p> <p>11 doing a randomized, controlled trial.</p> <p>12 Q. You've supervised trials trying</p> <p>13 to -- attempting to treat autism with a</p> <p>14 marijuana derivative, correct?</p> <p>15 A. I am involved in a number of</p> <p>16 different trials that look at different</p> <p>17 components that affect both the</p> <p>18 endocannabinoid system and the</p> <p>19 phytocannabinoid system. I have not</p> <p>20 conducted a trial with medical marijuana.</p> <p>21 I have conducted a</p> <p>22 placebo-controlled trial with cannabidiol,</p> <p>23 and I'm conducting another placebo-controlled</p> <p>24 trial with a different compound. And I will</p> <p>25 be conducting another placebo-controlled</p>

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1 trial with a FAAH inhibitor that affects the
 2 endocannabinoid system, but I have not
 3 conducted a trial with medical marijuana.
 4 Q. Okay. Dr. Hollander, with
 5 respect to strength of association, you view
 6 the strength of a perceived association not
 7 by the magnitude but by the statistical
 8 significance, correct?
 9 A. No.
 10 Q. Okay. Why not?
 11 A. Because there are different
 12 factors to contin -- to sort of evaluate and
 13 to consider in terms of looking at strength
 14 of association. Statistical significance may
 15 be one factor but certainly not the only
 16 factor.
 17 Q. Turn to page 8, please.
 18 A. Okay.
 19 Q. You see "Strength of
 20 Association," part E?
 21 A. Yes.
 22 Q. Okay.
 23 A. Right.
 24 Q. Third sentence down. "I view
 25 the strength of perceived association not by

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1 magnitude but by statistical significance in
 2 determining causality."
 3 Do you see those words?
 4 A. Yes.
 5 Q. You typed those, right?
 6 A. That's correct.
 7 Q. Okay. You just disagreed --
 8 you're arguing with yourself now?
 9 A. I'm not arguing with myself,
 10 and I -- so I'm stating that effect size or
 11 odds ratio in and of itself, so magnitude of
 12 the effect, is not the only factor in
 13 considering strength of association.
 14 So even if the magnitude of
 15 odds ratio or a relative risk is moderate, if
 16 it reaches statistical significance or if
 17 it's repeated over and over and over again,
 18 then it would be a -- demonstrate a strong
 19 association.
 20 Q. Did I read the words on the
 21 page in your report on page 8, Exhibit 52,
 22 correctly?
 23 A. Well, I believe you read the
 24 words on the page. "I view the strength of a
 25 perceived association not by magnitude but by

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1 statistical significance in determining
 2 causality."
 3 That's correct.
 4 Q. Okay.
 5 A. However, that's not the only
 6 factor. So statistical significance may be
 7 one factor, but as we've discussed
 8 previously, consistency, confidence
 9 intervals, replication, may be other factors.
 10 But this is -- this is correct,
 11 this sentence, as you read it.
 12 Q. Okay. And so when you answered
 13 that you disagreed with that sentence
 14 beforehand, you take that back, correct?
 15 MR. DOVEL: Objection. Form.
 16 THE WITNESS: I would say that
 17 it depends on -- it depends.
 18 QUESTIONS BY MR. MURDICA:
 19 Q. Okay.
 20 A. So, yes, statistical
 21 significance may be more important than
 22 magnitude, but statistical significance is
 23 not the whole story. That's my answer.
 24 Q. Okay. On page 11 you say,
 25 "Ultimately" -- are you on page 11?

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1 A. I'm on page 11, yeah.
 2 Q. First paragraph, last sentence.
 3 I want to make sure you wrote this.
 4 "Ultimately, I did not have
 5 sufficient time to complete a written
 6 analysis of each of the studies in sufficient
 7 detail."
 8 Did I read that correctly?
 9 A. You read it correctly.
 10 Q. Okay. Now, Dr. Hollander, why
 11 didn't you have time to read the studies?
 12 MR. DOVEL: Objection to form.
 13 THE WITNESS: I did have time
 14 to read the studies.
 15 QUESTIONS BY MR. MURDICA:
 16 Q. Okay. Why didn't you have time
 17 to complete a written analysis of the
 18 studies?
 19 A. I had time to read the studies,
 20 to process the information, to understand the
 21 information in detail.
 22 What I didn't have time to do
 23 is an approach such as Dr. Baccarelli did
 24 with a navigation guide where he weighted
 25 each of the different studies on a number of

<p style="text-align: right;">Page 174</p> <p>1 different criteria. That I -- that I did not</p> <p>2 have time to do.</p> <p>3 Q. Dr. Hollander, you were first</p> <p>4 retained by the plaintiffs' lawyers here</p> <p>5 months ago, correct?</p> <p>6 A. I think it was around</p> <p>7 February 23rd.</p> <p>8 Q. Right.</p> <p>9 So you didn't have time between</p> <p>10 February and July to complete a written</p> <p>11 analysis of the studies?</p> <p>12 A. I had time to read all of the</p> <p>13 studies. I had time to process the</p> <p>14 information of all of the studies. I did not</p> <p>15 have time to weight each study on a number of</p> <p>16 different metrics. And in that case, I</p> <p>17 relied on Dr. Baccarelli's navigation guide</p> <p>18 to do that.</p> <p>19 Q. Okay. Have you, Dr. Hollander,</p> <p>20 ever used the navigation guide in any of your</p> <p>21 publications?</p> <p>22 A. No.</p> <p>23 Q. Had you ever heard of the</p> <p>24 navigation guide before you read</p> <p>25 Dr. Baccarelli's report?</p>	<p style="text-align: right;">Page 176</p> <p>1 different studies on different variables, and</p> <p>2 integrating that into my practice. So the</p> <p>3 answer is yes.</p> <p>4 Q. Okay. So that wasn't my</p> <p>5 question.</p> <p>6 A. Okay.</p> <p>7 Q. My question was, prior to being</p> <p>8 involved in this litigation, have you ever</p> <p>9 read a publication that utilized the</p> <p>10 navigation guide?</p> <p>11 A. I -- you know, I don't recall</p> <p>12 whether or not I -- you know, I'm familiar</p> <p>13 with the term. I may have read a</p> <p>14 publication, but I don't recall that</p> <p>15 publication.</p> <p>16 Q. Okay.</p> <p>17 A. I haven't utilized that</p> <p>18 specific navigation guide myself.</p> <p>19 Q. Okay. Do you know when the</p> <p>20 navigation guide was first created?</p> <p>21 A. No.</p> <p>22 Q. Do you know if it was created</p> <p>23 30 years ago? 50 years ago? Five years ago?</p> <p>24 Any idea?</p> <p>25 A. I don't know.</p>
<p style="text-align: right;">Page 175</p> <p>1 A. I have heard of it before.</p> <p>2 I've never utilized it on my own.</p> <p>3 Q. Have you ever read a study</p> <p>4 prior to being involved in this litigation</p> <p>5 that utilized a navigation guide?</p> <p>6 A. In my practice, I frequently</p> <p>7 conduct a weight of the evidence, and so I do</p> <p>8 similar kinds of methods in order to, you</p> <p>9 know, ascribe different kinds of numerical</p> <p>10 factors to different weight of the evidence.</p> <p>11 So, for example, in the</p> <p>12 practice guidelines that I've been involved</p> <p>13 in, we do a very similar analysis. We do a</p> <p>14 pyramid or a hierarchy where we look at the</p> <p>15 different studies and different approaches.</p> <p>16 Then we weight each of those approaches in a</p> <p>17 different way, and then we utilize that</p> <p>18 information in order to recommend treatments</p> <p>19 of different conditions.</p> <p>20 Q. Do you remember my question?</p> <p>21 A. Well, I think your question</p> <p>22 is -- one is, did I ever use the navigation</p> <p>23 guide, and my answer was no.</p> <p>24 But I have conducted an</p> <p>25 approach which is similar, weighting</p>	<p style="text-align: right;">Page 177</p> <p>1 Q. Okay. Also on this page.</p> <p>2 "Accordingly, I have relied upon the analysis</p> <p>3 and assessment of the epi in Dr. Baccarelli's</p> <p>4 report."</p> <p>5 Did I read that correctly?</p> <p>6 A. Yes.</p> <p>7 Q. Okay. So before I asked you if</p> <p>8 you are rendering a causation opinion here</p> <p>9 based on the epidemiology separate and apart</p> <p>10 from Dr. Baccarelli. But you say here that</p> <p>11 you're relying on his analysis and overall</p> <p>12 assessment.</p> <p>13 Correct?</p> <p>14 MR. DOVEL: Objection. Form.</p> <p>15 THE WITNESS: Well, I mean, I</p> <p>16 think these sentences sort of describe</p> <p>17 this. So I reviewed the existing</p> <p>18 scientific research. I didn't have</p> <p>19 time to do a specific navigation guide</p> <p>20 analysis on each of the articles. I</p> <p>21 rely upon his analysis and overall</p> <p>22 assessment using that guide to weight</p> <p>23 each of the different articles.</p> <p>24 QUESTIONS BY MR. MURDICA:</p> <p>25 Q. Dr. Hollander, you didn't do</p>

<p style="text-align: right;">Page 178</p> <p>1 your own weighting of the articles; you're 2 relying on Dr. Baccarelli for that, correct? 3 A. I didn't include a weighting of 4 each of the different articles. I did 5 include a Bradford Hill analysis, which 6 incorporates the data from the analysis, to 7 inform and to guide the opinions that I 8 offer. 9 Q. So is your testimony here today 10 that you weighted the individual epidemiology 11 studies as part of your Bradford Hill 12 analysis, or you relied on Dr. Baccarelli's 13 weighting in doing your Bradford Hill 14 analysis? 15 A. Well, I'm relying upon his 16 navigation ratings of the epidemiology, but 17 I'm conducting my own Bradford Hill analysis 18 utilizing the information. 19 Q. Utilizing his ratings, correct? 20 A. Well, his ratings are one 21 component. His ratings of the articles give 22 you different strength weightings of each 23 individual article, which helps to inform my 24 Bradford Hill analysis. 25 Q. Okay. So in doing your</p>	<p style="text-align: right;">Page 180</p> <p>1 QUESTIONS BY MR. MURDICA: 2 Q. Okay. In the next paragraph, 3 you talk about Baker and Ji, right? That's 4 the next sentence? 5 A. That's correct. 6 Q. Okay. And you say, "Both 7 biomarkers serve as concrete measure of APAP 8 exposure." 9 Right? 10 A. That's correct. 11 Q. Were you aware that there was 12 an earlier Ji study that also used a 13 biomarker? 14 A. I believe that I have seen an 15 earlier Ji study. 16 Q. Do you know what it used as a 17 biomarker? 18 A. Perhaps you can show me that, 19 and I can take a look at it. 20 Q. Yeah, we're going to do that. 21 I was just seeing if you -- if you remember. 22 Do you know what biomarker Ji 23 2020 uses? 24 A. Yes. 25 Q. What's that?</p>
<p style="text-align: right;">Page 179</p> <p>1 Bradford Hill analysis, you used 2 Dr. Baccarelli's weighting of the articles 3 based on the navigation guide, correct? 4 A. That's correct. I -- 5 Q. Okay. 6 A. -- I review and rely on his 7 navigation weighting -- 8 Q. Okay. 9 A. -- in order for me to do my own 10 Bradford Hill analysis. 11 Q. Utilizing his data, correct? 12 A. Using his particular weighting 13 of the data, although I also conduct my own 14 review of the data. 15 Q. Okay. And the only 16 documentation, the only analysis, that we 17 have regarding the data is what you have in 18 here because you didn't time to do a separate 19 analysis, correct? 20 And what you testified to 21 today, fair? 22 MR. DOVEL: Objection. Form. 23 THE WITNESS: Well, that's 24 true. I didn't do a navigation 25 analysis on each of the articles.</p>	<p style="text-align: right;">Page 181</p> <p>1 A. Umbilical cord blood. 2 Q. And it says it right there on 3 the page, right? 4 A. That's correct. 5 Q. Okay. All right. And then if 6 we turn to page 12, you cite to Alemany, 7 right? 8 A. Yes. 9 Q. Okay. And you say that Alemany 10 found consistent positive association between 11 prenatal APAP exposure and ADHD and ASD, 12 correct? 13 A. That's correct. 14 Q. Okay. And we are going to look 15 at that one in a minute. 16 On page 13, you have a section 17 titled "JJCI-Produced Documents." 18 Let me know when you're on 19 page 13. It's at the very bottom. 20 A. Yes. 21 Q. Okay. You know that JJCI is 22 the defendant here, right? 23 A. That's correct. 24 Q. Okay. And you conclude the 25 paragraph on page 14, "Since these company</p>

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1 documents do not consist of any new or
 2 unknown primary evidence, I did not ascribe
 3 any additional weight to them."
 4 Right?
 5 A. Yes, I see that sentence.
 6 Q. Okay. But you wrote that,
 7 right?
 8 A. Yes.
 9 Q. Okay. So your intention here
 10 was to look at published data, not internal
 11 company documents, right?
 12 A. No.
 13 Q. Okay. What company documents
 14 did you ask for, and how did you get them?
 15 MR. DOVEL: As phrased, that is
 16 going to invade work product. You'll
 17 have to have to rephrase that
 18 question.
 19 QUESTIONS BY MR. MURDICA:
 20 Q. Dr. Hollander --
 21 A. Yes.
 22 Q. -- did you ask for company
 23 documents?
 24 A. Yes.
 25 Q. Okay. And did you ask for an

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1 index of what was available from the company?
 2 MR. DOVEL: That's going to
 3 invade --
 4 MR. MURDICA: Well, I'm not
 5 going to ask for the index.
 6 MR. DOVEL: -- work product,
 7 and so as a result, you're going to
 8 have to rephrase that question.
 9 MR. MURDICA: I'm not going to
 10 ask for the index. I'm just asking if
 11 he asked for it.
 12 MR. DOVEL: You're asking about
 13 communications. Under the federal
 14 rules, you're not allowed to do that,
 15 so I'll have to ask you to rephrase.
 16 QUESTIONS BY MR. MURDICA:
 17 Q. Dr. Hollander, do you know how
 18 many millions of pages of documents the
 19 defendants produced in this litigation?
 20 A. No.
 21 Q. Okay. Did you look at every
 22 document produced by the defendants in this
 23 litigation, to your knowledge?
 24 A. No.
 25 Q. Okay. And you know that,

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1 right?
 2 Because you've been involved in
 3 litigation. You know that millions of
 4 documents are produced, right?
 5 A. Well, it --
 6 MR. DOVEL: Objection. Form.
 7 THE WITNESS: If what you're
 8 saying is that there are millions of
 9 pages of documents, then I wouldn't
 10 have been able to review those
 11 millions of pages of documents.
 12 QUESTIONS BY MR. MURDICA:
 13 Q. You reviewed what was provided
 14 to you, correct?
 15 A. I asked for relevant documents,
 16 and I reviewed them.
 17 Q. Okay. So you just said, I want
 18 relevant documents, and that's what you --
 19 and you reviewed what you were given?
 20 MR. DOVEL: As phrased, that
 21 calls for communications with counsel.
 22 MR. MURDICA: Look, I'm really
 23 not trying to get into your
 24 communications, but I have to ask
 25 questions in this area.

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1 THE WITNESS: Could you
 2 rephrase that question, please?
 3 QUESTIONS BY MR. MURDICA:
 4 Q. Sure.
 5 Your testimony is that you
 6 asked for relevant company documents,
 7 correct?
 8 MR. DOVEL: That question --
 9 MR. MURDICA: He already
 10 testified to it.
 11 MR. DOVEL: Yes, but that was
 12 not in response to a question. As a
 13 result, I'm going to prohibit you from
 14 asking those questions, which you've
 15 not only agreed to in the protocol
 16 that was modified, you've also --
 17 subject to federal rules, you'll have
 18 to rephrase.
 19 MR. MURDICA: Look, I'll try
 20 again, but that's not what our
 21 agreement was.
 22 QUESTIONS BY MR. MURDICA:
 23 Q. Dr. Hollander, when you were
 24 provided -- after you were provided
 25 documents, did you ask any follow-up

<p style="text-align: right;">Page 186</p> <p>1 questions about additional documents from the 2 company?</p> <p>3 MR. DOVEL: Just as phrased, 4 you're asking about questions -- about 5 communications with counsel. You just 6 didn't put the word "counsel" in your 7 question.</p> <p>8 It's improper. You're going to 9 have to rephrase.</p> <p>10 QUESTIONS BY MR. MURDICA:</p> <p>11 Q. Dr. Hollander, how many pages 12 of company documents did you review in 13 preparation of your report and rebuttal 14 report?</p> <p>15 A. I don't recall.</p> <p>16 Q. Okay. Was it thousands?</p> <p>17 A. I don't think it was thousands.</p> <p>18 Q. You don't have any 19 recollection?</p> <p>20 A. I don't -- I don't think I 21 reviewed thousands of documents.</p> <p>22 Q. And in your regular work when 23 you're doing analyses to publish in the 24 scientific literature, do you get discovery 25 from manufacturers involved in exposures</p>	<p style="text-align: right;">Page 188</p> <p>1 Q. Okay. And the forest plots 2 were some internal company pictorial where 3 they put point estimates on a chart with 4 confidence intervals, correct?</p> <p>5 A. Well, the forest plots are from 6 this Project Cocoon, and it's a visual 7 representation of the confidence intervals 8 with regards to different studies looking at 9 exposure and outcome. So there are different 10 forest plots for different outcomes.</p> <p>11 Q. And you can go get that data 12 from the studies themselves, and indeed you 13 looked at the studies themselves, correct?</p> <p>14 A. I have looked at the studies 15 themselves.</p> <p>16 I think one thing that's very 17 informative, actually, is by looking at the 18 visual representation of the confidence 19 intervals for the different studies all put 20 together, it provides a beautiful overview in 21 terms of the consistency and the direction of 22 the findings across multiple different 23 studies with different outcome measures.</p> <p>24 Q. And you could have done that 25 yourself based on the data, correct?</p>
<p style="text-align: right;">Page 187</p> <p>1 you're looking at?</p> <p>2 A. Well, I would review material 3 relevant to whatever question or hypothesis 4 I'm testing.</p> <p>5 Q. That's public, right? Public 6 material, correct?</p> <p>7 A. Well, I would say generally if 8 I'm publishing something, the -- well, the 9 material may be public, although obviously 10 there may be data that's not public that I 11 may review as well, as it relates to the 12 hypothesis of the question.</p> <p>13 Q. If you're employed by the 14 manufacturer in some sort, right? In some 15 way?</p> <p>16 A. Well, that would be one case.</p> <p>17 Q. Okay. And here, you said you 18 don't ascribe weight to the company 19 documents, correct?</p> <p>20 A. No. It says I did not ascribe 21 any additional weight.</p> <p>22 Q. Okay. You identify forest 23 plots, correct? That's what we're talking 24 about in this paragraph?</p> <p>25 A. That's correct.</p>	<p style="text-align: right;">Page 189</p> <p>1 A. I think it's possible I could 2 have extracted the data from the individual 3 studies and then prepared a visual chart that 4 represents the different confidence intervals 5 and different outcome measures.</p> <p>6 I was appreciative of being 7 able to review that material.</p> <p>8 Q. All right.</p> <p>9 A. It was informative.</p> <p>10 Q. There was no data in what you 11 reviewed that was new, that you didn't have 12 from the literature itself, correct?</p> <p>13 A. Yes. Each of the -- I guess 14 each of the visual representations of the 15 confidence intervals could have been 16 extracted from the original data.</p> <p>17 Q. All right. Now, on the next 18 page you have your strength of association 19 section.</p> <p>20 A. Yes.</p> <p>21 Q. And in the third sentence you 22 say, "Importantly, the association between 23 APAP and exposure and ASD and ADHD has been 24 found consistently in meta-analyses and 25 systemic reviews," correct?</p>

<p style="text-align: right;">Page 190</p> <p>1 A. Systematic reviews.</p> <p>2 Q. And systematic reviews.</p> <p>3 And the first study you cite is</p> <p>4 Masarwa 2018, correct?</p> <p>5 A. Correct.</p> <p>6 Q. And this came up earlier</p> <p>7 because you volunteered that this is in your</p> <p>8 book chapter on autism, correct?</p> <p>9 A. Correct.</p> <p>10 Q. Okay. So let's take a look at</p> <p>11 Masarwa. You know what, I'm going to mark it</p> <p>12 in a second. I have a question first.</p> <p>13 To your recollection, Masarwa</p> <p>14 supports your point here that there's an</p> <p>15 association between APAP exposure and ASD,</p> <p>16 correct?</p> <p>17 A. Well, in this paragraph, as</p> <p>18 it's describing it, it talks about the</p> <p>19 association between prenatal APAP exposure</p> <p>20 and ASD and ADHD outcomes.</p> <p>21 Q. Right.</p> <p>22 So both of them. Masarwa</p> <p>23 supports your opinion on causation for both</p> <p>24 of them, correct?</p> <p>25 A. Well, both of them are listed</p>	<p style="text-align: right;">Page 192</p> <p>1 PubMed search?</p> <p>2 A. No.</p> <p>3 Q. Okay. Do you remember the</p> <p>4 search terms?</p> <p>5 A. I remember -- well, let me see</p> <p>6 if I specified in any of the written material</p> <p>7 what the search terms were that I used.</p> <p>8 Q. In medical literature, that's</p> <p>9 usually -- when there's a search, that's</p> <p>10 usually what the authors do, right? They</p> <p>11 explain how they searched and what they</p> <p>12 searched and what terms they used?</p> <p>13 A. Right. You specify what the</p> <p>14 databases are, and you specify what the terms</p> <p>15 are, right.</p> <p>16 I don't see a description of</p> <p>17 the search terms.</p> <p>18 Q. Okay. And sitting here today,</p> <p>19 you don't remember what your search terms</p> <p>20 were, right?</p> <p>21 A. Well, I can tell you what I</p> <p>22 would have entered into it, but I don't</p> <p>23 recall specifically. And I'm not able to</p> <p>24 find, but I could look for it a little bit</p> <p>25 more, whether there's a description of the</p>
<p style="text-align: right;">Page 191</p> <p>1 in the sentences above the citation.</p> <p>2 Q. Right.</p> <p>3 These are your words, right?</p> <p>4 A. Yes.</p> <p>5 Q. Okay. Did you conduct the</p> <p>6 literature analysis yourself?</p> <p>7 A. Yes.</p> <p>8 Q. Did you conduct the literature</p> <p>9 search yourself?</p> <p>10 A. Yes.</p> <p>11 Q. Okay. How did you do it?</p> <p>12 A. I did that by putting in search</p> <p>13 terms relating to exposure and outcome.</p> <p>14 Q. And where did you put the</p> <p>15 search terms?</p> <p>16 A. To searchable databases such as</p> <p>17 PubMed.</p> <p>18 Q. Okay. And you did that after</p> <p>19 you issued your initial report and before the</p> <p>20 rebuttal, correct?</p> <p>21 A. No.</p> <p>22 Q. When did you do the PubMed</p> <p>23 search?</p> <p>24 A. Prior to my initial report.</p> <p>25 Q. Okay. And did you save the</p>	<p style="text-align: right;">Page 193</p> <p>1 search terms.</p> <p>2 Q. Okay. If you end up finding it</p> <p>3 at any point today, let us know.</p> <p>4 A. Okay.</p> <p>5 (Hollander Exhibit 53 marked</p> <p>6 for identification.)</p> <p>7 QUESTIONS BY MR. MURDICA:</p> <p>8 Q. In the meantime, I'm going to</p> <p>9 mark this as Exhibit 53.</p> <p>10 Dr. Hollander, do you now have</p> <p>11 in front of you what's been marked as</p> <p>12 Exhibit 53?</p> <p>13 A. Yes.</p> <p>14 Q. Okay. Do you recognize</p> <p>15 Exhibit 53 as the 2018 Masarwa study that you</p> <p>16 brought up earlier this morning and that we</p> <p>17 just saw in your rebuttal report?</p> <p>18 A. Yes.</p> <p>19 Q. When is the last time you</p> <p>20 reviewed this study?</p> <p>21 A. I guess prior to my rebuttal</p> <p>22 report.</p> <p>23 Q. Okay. Do you recall, sitting</p> <p>24 here today, if this study -- if this -- this</p> <p>25 is a meta-analysis, right?</p>

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1 A. Yes.

2 Q. Okay.

3 A. It's a systematic review

4 meta-analysis and meta-regression analysis of

5 cohort studies.

6 Q. Sitting here today, do you

7 recall if Masarwa, in 2018, controlled for

8 genetic factors?

9 A. Let me take a look.

10 Q. And, Dr. Hollander, I know

11 there's a question pending, but you're -- you

12 grabbed something.

13 What is that? It doesn't look

14 familiar to me.

15 A. This is a summary table of the

16 different individual articles that was

17 prepared by Andrea Baccarelli.

18 Q. So you printed and brought with

19 you today a marked-up copy of

20 Dr. Baccarelli's summary tables of the

21 articles?

22 A. Yes.

23 Q. Okay.

24 A. However, I don't believe that

25 this, as a meta-analysis, is in the summary

Page 195

1 table.

2 Q. Can you say that again?

3 A. I don't believe that this, as a

4 meta-analysis, is included in the summary

5 table.

6 Q. In other words, what you're

7 looking at --

8 A. Is a summary table of the

9 individual studies as opposed to the

10 meta-analysis that utilizes pooled data from

11 the individual studies.

12 Q. Okay. So first of all, let's

13 mark that as Exhibit 54.

14 MR. DOVEL: Well, you can mark

15 the copy, but that's his --

16 MR. MURDICA: Sure, yeah, we'll

17 get -- we'll make copies of it.

18 MR. DOVEL: Yeah, that's going

19 to remain with him. We're not

20 actually going to mark that. We can

21 mark the copy.

22 MR. MURDICA: Okay. We'll make

23 and mark a copy. Yeah, we'll

24 photocopy it.

25 (Hollander Exhibit 54 marked

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1 for identification.)

2 QUESTIONS BY MR. MURDICA:

3 Q. Okay. Back to Exhibit 53.

4 So I -- let me go back to my

5 original question. I think I have your

6 answer.

7 But as far as you know,

8 Dr. Hollander, Masarwa 2018 has not

9 controlled for genetic factors, correct?

10 A. No, I did not say that.

11 Q. Oh, I'm sorry. That was my

12 question.

13 A. Okay.

14 Q. Did Masarwa control for

15 genetics?

16 A. Well, let's take a look at this

17 meta-analysis and see what he does.

18 Well, in the -- in the methods

19 underneath the meta-aggression, they talk

20 about covarying for a whole range of

21 different factors. But I don't believe that

22 they -- this is not a -- well, let's see what

23 they have here.

24 So they -- you know, they

25 control for age at follow-up, fever, maternal

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1 age at birth, smoking, socioeconomic,

2 latitude, duration. And they -- you know,

3 they look at them to understand confounders.

4 Q. Dr. Hollander, would you prefer

5 to go off the record and take some time to

6 review it?

7 MR. DOVEL: No, we're not going

8 to go off the record.

9 THE WITNESS: No, I'm almost

10 there. I've been able to review most

11 of it.

12 Well, they do comment on it.

13 So first, as I mentioned, one

14 of the strengths of this is that they

15 covary for a long list of factors, and

16 they find that the association remains

17 significant despite covarying for a

18 broad range of factors.

19 Then they talk about -- they

20 mention this Brandlistuen report:

21 "Increased risk for neurodevelopmental

22 disorders despite using a sib-matched

23 analysis design, which would be

24 expected to minimize the effect of

25 maternal characteristics on the

<p style="text-align: right;">Page 198</p> <p>1 observed observation."</p> <p>2 So they comment on that.</p> <p>3 QUESTIONS BY MR. MURDICA:</p> <p>4 Q. And do you agree with that,</p> <p>5 Dr. Hollander, that a sib-match design was a</p> <p>6 good -- is a strong design?</p> <p>7 A. Well, I would say that it</p> <p>8 depends.</p> <p>9 So it's one approach to try to</p> <p>10 control for genetic or familial factors. And</p> <p>11 there is one study that, you know, shows that</p> <p>12 in attempting to do that, there's still a</p> <p>13 strong association.</p> <p>14 But there are real problems</p> <p>15 with the sib-pair approach. And, you know,</p> <p>16 the huge problem with that is that it</p> <p>17 essentially negates the effects of mediators</p> <p>18 and moderators. And I'd like to give you a</p> <p>19 little explanation of that.</p> <p>20 Q. You can, Doctor, when your</p> <p>21 counsel asks you a question. But I was --</p> <p>22 let's stick to my original question, which is</p> <p>23 that -- did this meta-analysis control for</p> <p>24 genetics?</p> <p>25 A. The meta-analysis discusses</p>	<p style="text-align: right;">Page 200</p> <p>1 they don't -- they control for a large</p> <p>2 number of different factors. And they</p> <p>3 find even for controlling many of</p> <p>4 these factors, the findings persist,</p> <p>5 so...</p> <p>6 QUESTIONS BY MR. MURDICA:</p> <p>7 Q. Dr. Hollander, did you see</p> <p>8 anything here in Masarwa that controlled for</p> <p>9 parental ADHD or ASD?</p> <p>10 A. I don't see that they conducted</p> <p>11 any -- like a stratification analysis, for</p> <p>12 example, on those particular factors.</p> <p>13 Q. Okay. Dr. Hollander, do you</p> <p>14 see anything in Masarwa 2018 that controlled</p> <p>15 for paternal age?</p> <p>16 A. Actually, let's take a look at</p> <p>17 that because I do...</p> <p>18 Well, they do control for</p> <p>19 maternal age.</p> <p>20 Q. Do you remember my question?</p> <p>21 A. Was it paternal age?</p> <p>22 Q. Yes.</p> <p>23 A. I'm looking at it now, and I'm</p> <p>24 seeing if they controlled for paternal.</p> <p>25 It's a strong study because</p>
<p style="text-align: right;">Page 199</p> <p>1 that as a potential issue and then talks</p> <p>2 about how that has been controlled, and the</p> <p>3 findings persist in spite of that.</p> <p>4 However -- let me just finish</p> <p>5 here.</p> <p>6 MR. MURDICA: I know, Counsel,</p> <p>7 you said you don't want to go off the</p> <p>8 record, but I have a number of studies</p> <p>9 to go through, and it might save</p> <p>10 everybody time.</p> <p>11 THE WITNESS: Well, I don't --</p> <p>12 so -- I mean, this meta-analysis does</p> <p>13 not use a sib-pair approach. There</p> <p>14 are -- you know, there are problems</p> <p>15 with a sib-pair approach if there are</p> <p>16 mediators and moderators. It just</p> <p>17 wipes that out, so it's an</p> <p>18 inappropriate approach.</p> <p>19 However, they do discuss the</p> <p>20 potential for genetic factors, and</p> <p>21 then they review relevant literature</p> <p>22 relating to that. And they say that</p> <p>23 in that, the findings persist despite</p> <p>24 controlling for that.</p> <p>25 But that this study itself,</p>	<p style="text-align: right;">Page 201</p> <p>1 they used many, many different factors in</p> <p>2 their meta-regression.</p> <p>3 Let's see.</p> <p>4 No, it looks like they look at</p> <p>5 maternal age at birth, but I'm not sure that</p> <p>6 they included paternal age at birth.</p> <p>7 Q. Okay. So as far as you could</p> <p>8 tell, Dr. Hollander, they haven't controlled</p> <p>9 for paternal age, correct?</p> <p>10 A. I don't -- I don't see a</p> <p>11 listing of paternal age.</p> <p>12 Q. Okay.</p> <p>13 A. I do see the maternal age.</p> <p>14 Q. And the data here is</p> <p>15 observational only, right?</p> <p>16 A. Well, it's an observational</p> <p>17 study, but it's pooling different studies</p> <p>18 that have been conducted, including cohort</p> <p>19 studies, yeah.</p> <p>20 Q. Right.</p> <p>21 And the underlying data is</p> <p>22 observational data, correct?</p> <p>23 A. Right.</p> <p>24 Q. Okay. And notwithstanding,</p> <p>25 Dr. Hollander, you think this is a strong</p>

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1 study, correct?

2 A. It is very strong.

3 Q. Very strong study.

4 And all of the things you were

5 reading were intended to eliminate bias and

6 confounding, correct?

7 A. Yeah. They do a lot of work to

8 try to eliminate bias and confounding, and

9 they get a strong relationship for exposure

10 and outcomes, including, you know, age of the

11 child on follow-up and duration of exposure.

12 So they find a -- the dose-response

13 relationship here.

14 Q. Notwithstanding the authors

15 warn that there was evidence of heterogeneity

16 between the study estimates of the outcomes,

17 right?

18 A. Well, there's great

19 heterogeneity with each of the conditions,

20 and there's a range of different outcomes.

21 However, you know, what's

22 really remarkable about this is -- so they --

23 look, they have one, two, three, four, five

24 individual studies, right? And then they

25 have an overall relative risk here. And the

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1 visual is really strong, actually, for the

2 relative risk ratios for the pooled data.

3 Q. If you turn to the discussion

4 section --

5 A. Uh-huh.

6 Q. -- Dr. Hollander.

7 A. Yeah.

8 Q. About halfway down it says,

9 "However, results should be interpreted with

10 caution because there was evidence of

11 heterogeneity between study estimates of the

12 outcome."

13 Do you see that?

14 A. Can you direct me to the

15 paragraph?

16 Q. Sure.

17 Do you see the discussion

18 section?

19 A. Yeah, I do.

20 Q. It's on page 1822, halfway

21 down. "However," on the left column.

22 A. Right.

23 Q. That was my question before.

24 Do you agree with that?

25 A. Well, I guess the issue is also

Page 204

1 that -- so this first study, the Brandlistuen

2 2013 --

3 Q. Right.

4 A. -- is a relatively small study,

5 which is relatively weak. But I would say

6 that all of the other studies show a strong

7 positive association with confidence

8 intervals that don't cross 1.

9 So the -- you know, with the

10 exception of that study, there's not a lot of

11 heterogeneity. It looks like it's strong

12 data that's been replicated over and over,

13 which just grows when you pool the data

14 together with the bigger sample size.

15 Q. Dr. Hollander, the Brandlistuen

16 study you just mentioned, that's the one you

17 said earlier was a sib-control, correct?

18 A. Let me take a look, because

19 that's 2013?

20 Q. Well, you were reading it from

21 this article, but, sure.

22 A. Because that --

23 Q. Let the record reflect that

24 Dr. Hollander is going to Dr. Baccarelli's

25 tables to answer my question.

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1 A. Okay.

2 Q. Which will be marked as

3 Exhibit 54.

4 A. Let me take a look at that,

5 actually, because that's...

6 So, I mean, if you see it, it's

7 the -- it's the first one. It's 2013, so

8 it's earlier. And let's take a look at what

9 they have to say with regards to

10 heterogeneity later on, because...

11 So the -- I mean, this study is

12 really a strong study because they control

13 for so many different potential confounders.

14 They do a sensitivity analysis.

15 Q. Dr. Hollander, I don't mean to

16 interrupt, but are you talking about Masarwa

17 or Brandlistuen?

18 A. No, I'm talking about Masarwa.

19 Q. Okay. Earlier you testified

20 that Brandlistuen has a sibling-control

21 design.

22 A. Uh-huh.

23 Q. You don't recall that?

24 A. I do, actually.

25 Q. Okay.

<p style="text-align: right;">Page 206</p> <p>1 A. Yes.</p> <p>2 Q. That was my question.</p> <p>3 A. Right.</p> <p>4 Q. Okay.</p> <p>5 A. I do recall that.</p> <p>6 Q. And you gave testimony about</p> <p>7 how there could be a mediator in the</p> <p>8 sibling-control design. And my question for</p> <p>9 you is that if there's a mediator in the</p> <p>10 sibling-control design of an</p> <p>11 acetaminophen/autism/ADHD study, that would</p> <p>12 be -- that mediator would be present in</p> <p>13 whatever studies utilized sibling-control</p> <p>14 design, correct? For that same exposure and</p> <p>15 outcome.</p> <p>16 A. Well, so, let me see if I can</p> <p>17 try to interpret this -- the question in</p> <p>18 hand.</p> <p>19 So we're talking about the</p> <p>20 relationship between exposure and outcome,</p> <p>21 right? We're talking about some of the</p> <p>22 problems with a sib-pair approach.</p> <p>23 So let's say that</p> <p>24 acetaminophen, you know, functions as an</p> <p>25 anandamide reuptake inhibitor, so it enhances</p>	<p style="text-align: right;">Page 208</p> <p>1 because it would be something that persisted</p> <p>2 regardless of the study population, correct?</p> <p>3 If they're siblings?</p> <p>4 A. Well, that would be a reason</p> <p>5 why utilizing a sib-pair approach would --</p> <p>6 like a -- bias the study towards the null</p> <p>7 rather than away from the null.</p> <p>8 Q. Okay. If you turn to</p> <p>9 page 1824.</p> <p>10 Do you see the strengths and</p> <p>11 limitations section?</p> <p>12 A. Yes.</p> <p>13 Q. The second paragraph down,</p> <p>14 second sentence, please tell me if I've got</p> <p>15 this right. It says, "Only a limited number</p> <p>16 of studies were available for analysis, and</p> <p>17 all of the studies included were</p> <p>18 observational design. Most of the studies</p> <p>19 had some risk of bias, and the results</p> <p>20 indicated significant heterogeneity."</p> <p>21 Did I read that correctly?</p> <p>22 A. You read that correctly.</p> <p>23 Q. Okay. And I -- you agreed that</p> <p>24 they were observational. And do you agree</p> <p>25 that they have risk of bias?</p>
<p style="text-align: right;">Page 207</p> <p>1 endogenous endocannabinoid levels in the</p> <p>2 developing fetal brain. Let's say enhancing</p> <p>3 those endogenous cannabinoid levels work via</p> <p>4 the CB1, and also that FAAH, you know, the</p> <p>5 enzyme that, you know, creates this AM404 out</p> <p>6 of APAP, that there are genetic variations.</p> <p>7 Then the effects of APAP would only be</p> <p>8 recognized in those individuals who have</p> <p>9 variations of the CB1 receptor and variations</p> <p>10 in the FAAH receptor. So -- and that's a</p> <p>11 family or a genetic impact.</p> <p>12 If you utilize a sib-pair</p> <p>13 approach, then you'd take away those</p> <p>14 mediators of the CB1 and FAAH genetic</p> <p>15 polymorphisms, then you lose the results.</p> <p>16 So the problem there is that</p> <p>17 there's a true association. But if you do a</p> <p>18 sib-pair approach, it's impossible to</p> <p>19 determine that because you've effectively</p> <p>20 taken away the mediators that mediate that</p> <p>21 effect.</p> <p>22 Q. Right.</p> <p>23 And if that is in fact</p> <p>24 something that happens, that would persist in</p> <p>25 whatever sib-pair studies there were for --</p>	<p style="text-align: right;">Page 209</p> <p>1 A. Well, every study has a</p> <p>2 potential risk for bias, and that's why when</p> <p>3 you design a study and when you analyze the</p> <p>4 data, you need to control for potential bias.</p> <p>5 Q. And you disagree with them here</p> <p>6 where they say the results indicated</p> <p>7 significant heterogeneity.</p> <p>8 You don't see it, correct?</p> <p>9 A. Well, I really don't see much,</p> <p>10 actually. I see that there's a strong</p> <p>11 consistency of the findings with these</p> <p>12 studies, with one exception.</p> <p>13 Q. Okay. And two sentences</p> <p>14 down -- I had asked you about paternal age --</p> <p>15 it says, "In addition, ASD diagnosis is known</p> <p>16 to be strongly related to advancing paternal</p> <p>17 age."</p> <p>18 You agreed with that earlier</p> <p>19 toady when I asked you, right?</p> <p>20 A. That's correct.</p> <p>21 Q. Okay. And it says, "However,</p> <p>22 none of these studies included paternal age</p> <p>23 as a covariant."</p> <p>24 You just testified that</p> <p>25 that's -- you didn't see it in here, correct?</p>

<p>Page 210</p> <p>1 A. Well, I've testified that there 2 are -- they've adjusted for multiple 3 confounders, so they should be applauded for 4 that. But it -- including maternal age. But 5 it's true that they didn't covary for 6 paternal age. 7 Q. Right. 8 And that's one of the things 9 that you, Dr. Hollander, associate with the 10 outcomes of ASD and ADHD, correct? 11 A. Well, let's go over that again, 12 because I believe that that would actually 13 bias it towards the null rather than away 14 from the null. 15 Q. Okay. 16 A. So it wouldn't provide a -- it 17 would not provide for a differential. It 18 would be a nondifferential. 19 Q. All right. So in your view, 20 Masarwa's concern about paternal age here is 21 unjustified, correct? 22 A. No, I think that Masarwa is 23 doing a good time -- a good job, actually. 24 So when you author an article 25 like this, you always have to consider the</p>	<p>Page 212</p> <p>1 And they've done that as well. 2 Q. And you think they've done a 3 great job at that, right? 4 A. I think they've done an 5 excellent job at that. 6 Q. Okay. 7 A. I mean, no study can do endless 8 amounts of covary. And you always have to 9 read these studies with some appropriate 10 level of detail to look at the strengths and 11 the limitations. And then the authors need 12 to discuss the strengths and the limitations. 13 But discussing the strengths 14 and the limitations don't negate the findings 15 of the study. 16 Q. Okay. Dr. Hollander, if you 17 can go to the final page where it says, 18 "Implications for policy and practice," I 19 have two more questions for you on this 20 article. 21 A. Right. 22 Q. Halfway down, it says -- do you 23 see where it says, "Our results indicate"? 24 A. Yes. 25 Q. "Our results indicate a small</p>
<p>Page 211</p> <p>1 strengths and the weaknesses of any 2 individual study, and then you want to try to 3 control for any of those potential 4 confounders or bias. 5 So, for example, if you look at 6 the design of these studies, they collect 7 information about exposure during pregnancy, 8 and then they look at different measures for 9 outcome many years later. 10 The cohort nature of the 11 studies, for example, control for things like 12 recall bias as an example. 13 The design of each of the 14 individual studies controls for various types 15 of bias. 16 Now, what they're doing here is 17 they're pooling the data from the different 18 studies. And in addition to doing that, then 19 they're trying to look at other potential 20 sources that could be confounders or bias. 21 And then one of the ways to 22 deal with that, in addition to the original 23 designs of the study, is then to, in a 24 statistical fashion, try to control for those 25 potential confounders by covarying for them.</p>	<p>Page 213</p> <p>1 increase in the risks for ADHD and ASD in the 2 offspring of women exposed to acetaminophen 3 during pregnancy." 4 Did I read that correctly? 5 A. Correct. 6 Q. And do you agree that it's 7 small? 8 A. No. I agree that, you know, if 9 you look at it, they talk about, you know, 10 statistically significant elevated risks that 11 vary depending on the outcome. So they talk 12 about elevated relative risks that reach 13 statistical significance. 14 I guess we're getting back to 15 that sentence that you read before in terms 16 of the magnitude of the effect versus the 17 statistical significance. 18 But if you look at one of the 19 points that I was making is -- if you look at 20 these things and the consistency of the 21 findings, they're replicated over and over 22 again, and so they're statistically 23 significant. You have odds ratios that are 24 above 1. And then there -- so they're -- 25 they're replicated as well, you know.</p>

<p style="text-align: right;">Page 214</p> <p>1 Q. Okay. The next sentence where 2 I just read, it says, "However, due to the 3 high heterogeneity in the observed 4 association, the potential for exposure and 5 outcome misclassification and the possibility 6 of residual confounding" -- 7 A. Right. 8 Q. -- et cetera, et cetera, 9 "further investigation evaluating the 10 observed link is warranted." 11 A. Right. 12 Q. Do you, Dr. Hollander, agree 13 that at this point -- that Masarwa, in 2018, 14 further investigation evaluating the observed 15 link is warranted? 16 MR. DOVEL: Objection. Form. 17 THE WITNESS: Well, I think 18 that the -- so this was published in 19 2018. They talk about the potential. 20 So, I mean, it's -- so again, you 21 know, there is a -- you want to make 22 sure that you're -- that you -- that 23 you don't have misclassification. 24 There are various ways to prevent that 25 from happening, for example, such as</p>	<p style="text-align: right;">Page 216</p> <p>1 QUESTIONS BY MR. MURDICA: 2 Q. And, Dr. Hollander, you see 3 that genetic factors are listed as one 4 possibility for residual confounding, right? 5 A. That's right. 6 Q. And you agreed with me earlier 7 that parental ASD and ADHD diagnoses are not 8 controlled for here, correct? 9 A. I don't believe that it was -- 10 they didn't use that as a -- to covary. 11 Q. And if the parents have ASD or 12 ADHD, that is a genetic factor, correct? 13 A. It's a -- well, it's a familial 14 factor. 15 Q. Sure. Familial factor. 16 Okay. Do you see the next 17 sentence? "Considering the significant 18 limitations inherent in the available 19 research, we believe care should be taken to 20 avoid overstating the significance of the 21 results of our analysis because this could 22 promote unnecessary anxiety among pregnant 23 women." 24 A. I see that. 25 Q. Do you see that?</p>
<p style="text-align: right;">Page 215</p> <p>1 prospective design of these studies. 2 The possibility of residual 3 confounding, yeah, I mean, they did -- 4 they did actually -- so they talk 5 about maternal characteristics. They 6 did covary for maternal age. 7 It is true that you do want to 8 address these different issues, right? 9 So, for example, maternal 10 characteristics. And this is 11 something that's come up. It is a 12 good idea to take a look and see 13 whether those maternal characteristics 14 are a factor as a cofounder. Are they 15 related to both the exposure and the 16 outcome. 17 So studies like Lupattelli have 18 tried to address that where they look 19 at the maternal characteristics, and 20 then they try to determine whether or 21 not the association between the 22 exposure and the outcome persists even 23 if you control for those maternal 24 characteristics. 25</p>	<p style="text-align: right;">Page 217</p> <p>1 Okay. Did I read that 2 correctly? 3 A. You read it correctly. 4 Q. And in your practice, you are 5 asked by some of your patients if they should 6 continue their medicine to treat their OCD, 7 autism, and other diagnoses like that, 8 correct? While they're pregnant. During 9 pregnancy. 10 A. Yes, I do have mothers who ask 11 me questions about whether or not they should 12 take medicines during pregnancy, yeah. And 13 then we do engage in a risk versus benefit 14 discussion. 15 Q. Right. 16 And they're asking you about 17 medicines you prescribe, right? 18 A. They may be asking about 19 medicines that I prescribe, but -- or they 20 may be asking me about other medicines that 21 they could be taking over the counter as 22 well. 23 Q. But it's to treat -- they're 24 asking you about medicines to treat the 25 symptoms of the conditions that you're</p>

<p style="text-align: right;">Page 218</p> <p>1 treating them for, correct?</p> <p>2 A. No, not necessarily. I mean,</p> <p>3 they're asking me about risk in terms of</p> <p>4 offspring, and they're asking me about risk</p> <p>5 versus benefit of them taking various kinds</p> <p>6 of medicines during pregnancy. And they want</p> <p>7 to engage in a discussion about the accurate</p> <p>8 risks versus the benefits of taking any of</p> <p>9 the compounds versus the potential -- the</p> <p>10 negative outcome of having a child with ASD</p> <p>11 or ADHD.</p> <p>12 Q. Okay. So you're talking about</p> <p>13 any medications at all, as if you were their</p> <p>14 obstetrician, right, Doctor?</p> <p>15 A. Well, I'm saying that in my</p> <p>16 practice I have people coming to me all the</p> <p>17 time, and I engage in a risk versus benefit</p> <p>18 discussion with regards to different things</p> <p>19 that they're taking because there may be</p> <p>20 benefits to the mother, there may be risks to</p> <p>21 the fetus. And to make an informed decision,</p> <p>22 I think that the clinicians and the patients</p> <p>23 and the families need to have accurate and</p> <p>24 up-to-date information in order to engage in</p> <p>25 that conversation.</p>	<p style="text-align: right;">Page 220</p> <p>1 A. I see that. And they're --</p> <p>2 they are engaging in a risk versus benefit</p> <p>3 kind of analysis where they're saying you</p> <p>4 don't want to promote unnecessary anxiety; on</p> <p>5 the other hand, that this is important</p> <p>6 information, and so additional work should be</p> <p>7 done to do a causal analysis, yes.</p> <p>8 Q. Okay. And do you agree with</p> <p>9 them that as of this article in 2018, a</p> <p>10 causal link between exposure to acetaminophen</p> <p>11 and neurodevelopmental disorders cannot be</p> <p>12 established?</p> <p>13 MR. DOVEL: Mr. Murdica, is</p> <p>14 that beyond the scope of this phase,</p> <p>15 do you think, or not? What do you</p> <p>16 think?</p> <p>17 MR. MURDICA: I think it's a</p> <p>18 causation question.</p> <p>19 MR. DOVEL: Is it specific</p> <p>20 causation or general causation? How</p> <p>21 would you categorize that?</p> <p>22 MR. MURDICA: I would</p> <p>23 categorize that as how that</p> <p>24 contributes to his body of knowledge</p> <p>25 on causation. If he agrees that this</p>
<p style="text-align: right;">Page 219</p> <p>1 Q. And I take it, Dr. Hollander,</p> <p>2 you don't -- you agree that you shouldn't</p> <p>3 promote unnecessary anxiety among pregnant</p> <p>4 women by overstating risks, correct?</p> <p>5 A. No. I think it's part of the</p> <p>6 risk versus benefit ratio discussion, that's</p> <p>7 correct. So you don't want to cause</p> <p>8 unnecessary risk by freaking out the parents,</p> <p>9 and you want to be able to engage in an</p> <p>10 accurate and informative discussion of risks</p> <p>11 and benefits. But to do that, you need to</p> <p>12 have accurate information about the -- both</p> <p>13 the benefits and the risks.</p> <p>14 Q. Okay. Doctor --</p> <p>15 A. Absolutely.</p> <p>16 Q. Dr. Hollander, in the next</p> <p>17 sentence, do you see that these authors, in</p> <p>18 2018, say that a causal link between exposure</p> <p>19 to acetaminophen and neurodevelopmental</p> <p>20 disorders --</p> <p>21 A. Right.</p> <p>22 Q. -- cannot be established at</p> <p>23 this point? This is in 2018 they're saying</p> <p>24 this.</p> <p>25 Do you see that?</p>	<p style="text-align: right;">Page 221</p> <p>1 isn't enough right now.</p> <p>2 MR. DOVEL: So we can ask all</p> <p>3 your witnesses about the same subject.</p> <p>4 MR. MURDICA: Sure.</p> <p>5 MR. DOVEL: Okay.</p> <p>6 THE WITNESS: Well, I'm saying</p> <p>7 that the authors are being</p> <p>8 appropriately cautious and</p> <p>9 conservative. And what they're saying</p> <p>10 here is that careful inspection of</p> <p>11 policies -- and I guess they also mean</p> <p>12 package inserts as well, patient</p> <p>13 leaflets, because there's unsupervised</p> <p>14 and widespread use of acetaminophen,</p> <p>15 and it's claimed to be a safe,</p> <p>16 nonprescription medication.</p> <p>17 However, they're showing a</p> <p>18 strong and significant association</p> <p>19 that persists, despite various kinds</p> <p>20 of ways to measure or to address</p> <p>21 confounders or sources of -- sources</p> <p>22 of bias that persist despite all of</p> <p>23 that.</p> <p>24 So it's a signal that's of</p> <p>25 concern, and that more work needs to</p>

<p style="text-align: right;">Page 222</p> <p>1 be done in order to reach a causal</p> <p>2 analysis.</p> <p>3 QUESTIONS BY MR. MURDICA:</p> <p>4 Q. And my question for you,</p> <p>5 Dr. Hollander, is if you agree with that.</p> <p>6 A. Well, I would say --</p> <p>7 MR. DOVEL: Let me insert an</p> <p>8 objection.</p> <p>9 Objection. Form.</p> <p>10 You can respond.</p> <p>11 THE WITNESS: So I would say</p> <p>12 that in my causal analysis, you know,</p> <p>13 I was able to look at the results of</p> <p>14 this study along with multiple other</p> <p>15 meta-analytic and systemic reviews and</p> <p>16 individual studies. I was also able</p> <p>17 to review the animal literature.</p> <p>18 And then I was able to use a</p> <p>19 standardized methodology to be able to</p> <p>20 review all of that to determine a</p> <p>21 causal relationship. So I agree that</p> <p>22 they didn't do that here.</p> <p>23 What they did is they took a</p> <p>24 series of individual epidemiology</p> <p>25 studies, they pooled the data, they</p>	<p style="text-align: right;">Page 224</p> <p>1 QUESTIONS BY MR. MURDICA:</p> <p>2 Q. Okay. Dr. Hollander, can</p> <p>3 you --</p> <p>4 MR. DOVEL: If you're going to</p> <p>5 move to another topic, we should take</p> <p>6 a break.</p> <p>7 MR. MURDICA: Sure.</p> <p>8 MR. DOVEL: Let's go off the</p> <p>9 record.</p> <p>10 VIDEOGRAPHER: The time right</p> <p>11 now is 2:29 p.m. We are off the</p> <p>12 record.</p> <p>13 (Off the record at 2:29 p.m.)</p> <p>14 VIDEOGRAPHER: The time right</p> <p>15 now is 2:40 p.m. We are back on the</p> <p>16 record.</p> <p>17 QUESTIONS BY MR. MURDICA:</p> <p>18 Q. Welcome back, Dr. Hollander.</p> <p>19 A. Thank you.</p> <p>20 Q. Are you ready to proceed?</p> <p>21 A. Yes, I am.</p> <p>22 Q. Okay. Dr. Hollander, we</p> <p>23 discussed the concept of heterogeneity in the</p> <p>24 context of Exhibit 53, the Masarwa 2018</p> <p>25 study, and the authors noted heterogeneity.</p>
<p style="text-align: right;">Page 223</p> <p>1 wanted to see whether it persisted</p> <p>2 even when they controlled for various</p> <p>3 kind of factors. It did persist.</p> <p>4 They recognize that this is sort of</p> <p>5 widely used, but they're getting a</p> <p>6 signal, and they're suggesting that</p> <p>7 people should really do all the work</p> <p>8 to establish causality in order to be</p> <p>9 able to change the risk versus benefit</p> <p>10 discussion and the labeling relating</p> <p>11 to this product.</p> <p>12 QUESTIONS BY MR. MURDICA:</p> <p>13 Q. So in your analysis,</p> <p>14 Dr. Hollander, this study, this Masarwa 2018</p> <p>15 study, wasn't enough to make you determine</p> <p>16 that there's a causal relationship between</p> <p>17 acetaminophen and ASD and ADHD, correct?</p> <p>18 MR. DOVEL: Objection. Form.</p> <p>19 THE WITNESS: Well, I'm saying</p> <p>20 that this is strong evidence. I</p> <p>21 utilized this in, you know, performing</p> <p>22 my analysis in causation. So it's one</p> <p>23 piece of strong evidence. It's not</p> <p>24 the only evidence.</p> <p>25</p>	<p style="text-align: right;">Page 225</p> <p>1 You maybe didn't see it that way.</p> <p>2 But here's my question. Can</p> <p>3 you tell us how you defined heterogeneity in</p> <p>4 the context of a meta-analysis?</p> <p>5 A. I guess -- well, heterogeneity</p> <p>6 means different presentations, different</p> <p>7 components.</p> <p>8 So I guess they look -- they</p> <p>9 look at these five studies over and over</p> <p>10 again from different perspective, and they're</p> <p>11 all cohort studies. You know, they differ in</p> <p>12 terms of the year that they were conducted</p> <p>13 and they differ in terms of the outcome.</p> <p>14 So, you know, some of these</p> <p>15 things look at things like hyperactivity.</p> <p>16 Some of them look at conduct disorder. Some</p> <p>17 of them look at ASD. Some of them look at</p> <p>18 ADHD.</p> <p>19 I would say that there's</p> <p>20 heterogeneity with it -- as it relates to the</p> <p>21 outcome -- the outcome or the domains of</p> <p>22 interest, and I would say that there's some</p> <p>23 variation as it relates to the risk ratios as</p> <p>24 well.</p> <p>25 Q. Okay. So your definition in</p>

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1 the context of Exhibit 52 is that
2 heterogeneity is difference in the outcome.
3 Some studies looked at ADHD; some studies
4 looked at ASD.

5 Is that -- is that your
6 testimony?

7 A. Well, there are, you know, a
8 whole range of different kinds of outcomes
9 that are looked at across these different
10 studies. I guess we could take a look and
11 see what's the context or how they use that
12 word "heterogeneity" here.

13 Q. Well, Doctor, I'm actually
14 asking you. How do you use -- what's your
15 definition of heterogeneity?

16 A. Heterogeneity --

17 MR. DOVEL: Let me insert an
18 objection.

19 Objection. Form.

20 You can respond.

21 QUESTIONS BY MR. MURDICA:

22 Q. Okay.

23 A. Okay. Well, I would use
24 heterogeneity as a variation in presentation,
25 a variation in outcome or -- so as it relates

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1 to these neurodevelopmental disorders,
2 there's a lot of heterogeneity in terms of
3 the clinical symptom domains.

4 Q. Dr. Hollander --

5 A. Yes.

6 Q. -- in the context of
7 meta-analyses generally, does heterogeneity
8 describe differences in the studies in terms
9 of the methods of data observation and
10 collection and things like that?

11 A. Well, I think you have to
12 interpret it within the context that the word
13 is used.

14 So here they're talking about
15 heterogeneity in terms of the relative risk
16 for neurodevelopmental outcomes, and they
17 also describe that there are differences in
18 terms of the design, the setting, the
19 populations. So then they also talk about
20 the different tools as well.

21 So I guess you can have
22 heterogeneity as it relates to the results.
23 You can have heterogeneity as it results
24 {sic} to the design of the individual
25 studies. You could have heterogeneity in

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1 terms of the outcome.

2 Q. Okay. And since you disagreed
3 with the authors on the heterogeneity, I was
4 just asking what your definition is.

5 So if that's -- if you just
6 gave us your best answer, that's good enough
7 for me.

8 A. Well, so let me -- let me put
9 it this way, that if -- so actually, even in
10 the context here, they're referring to
11 heterogeneity in different ways. So they're
12 talking about -- so they're saying all of the
13 studies tended towards increased risk for
14 neurodevelopmental outcomes, but then they're
15 talking about significant heterogeneity,
16 which they say can be explained by
17 differences. And then they, you know -- they
18 talk about things like design, setting,
19 population.

20 So -- they actually are -- you
21 know, they're not saying that there are --
22 because they're -- even in this sentence,
23 they are saying all of the studies show
24 increased risk for neurodevelopmental
25 outcomes. So I guess I agree with them in

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1 that respect, yeah.

2 Q. Okay. So are you -- are you
3 broadening your definition of heterogeneity
4 compared to how you were answering before our
5 break?

6 A. Well, I'm -- I'm -- I've looked
7 at the article. I'm trying to understand
8 their use of the term, and I'm seeing that
9 they better define the term "heterogeneity"
10 in the discussion section, and then they talk
11 about it there, yeah.

12 Q. Dr. Hollander, have you ever
13 conducted a meta-analysis?

14 A. Well, I read meta-analyses and
15 interpret meta-analyses all the time. I'm
16 not sure that I have conducted a
17 meta-analysis where I've taken a series of
18 published studies and then I've pooled the
19 data and published it as a meta-analysis.

20 Q. So then would it be fair to
21 assume that you've never tried to analyze a
22 group of studies to determine whether the
23 data was homogeneous or heterogenous, right?

24 A. No. Because in my reading of
25 the meta-analysis, I would be able to address

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1 that.

2 Q. So I want to make sure I got

3 that answer right.

4 Your testimony is that you have

5 analyzed different published data sets to

6 determine if they're heterogeneous or

7 homogenous?

8 A. No, I didn't say that.

9 Q. Okay.

10 A. I said that I haven't myself

11 conducted meta-analytic studies but that I

12 read and interpret them all the time.

13 Q. Okay.

14 Earlier, before our last break,

15 you were talking about giving advice on

16 medication intake to pregnant women,

17 particularly pregnant patients of yours.

18 Do you recall that?

19 A. Yes. Either women who were

20 pregnant or women who were considering

21 becoming pregnant.

22 Q. Okay. And despite not being

23 board certified in obstetrics, you offer your

24 advice on any range of over-the-counter or

25 prescription medication for your patients in

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1 pregnancy, correct?

2 A. Well, I engage in a risk versus

3 benefit discussion with regard to

4 prescription and nonprescription medicines --

5 Q. Right.

6 A. -- with my patients.

7 Q. And you've done that with

8 respect to your patients and acetaminophen,

9 correct?

10 A. I have.

11 Q. Okay. And you tell your

12 patients now not to take acetaminophen,

13 correct?

14 A. No. I say that there are risks

15 and benefits of taking any medication during

16 pregnancy.

17 Q. Okay. Do you tell your

18 patients if -- if you have a patient that's

19 pregnant and has a migraine, do you -- and

20 they say, Dr. Hollander, can I take

21 acetaminophen, what do you say?

22 A. Well, I did offer an opinion

23 with regards to that in my initial expert

24 report, which is that I would say that for a

25 woman experiencing pain, I would tell them

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1 that there are potential benefits and

2 potential risks, but for the use of pain, the

3 risks may outweigh the benefits, and that I

4 would limit the amount of medication; that

5 they should take the absolute smallest number

6 of doses for the shortest period of time and

7 to consider other alternatives.

8 Q. Okay. So for one of your

9 pregnant patients experiencing migraine

10 during pregnancy, you would -- you would say

11 that the risks outweigh the benefits,

12 correct?

13 A. Well, I would inform her of

14 information with regards to increased risk of

15 neurodevelopmental outcomes, and I would say

16 that the risk -- there's a dose-response

17 relationship, so that increasing dose and

18 increasing duration would further exacerbate

19 those risks.

20 And then I would examine the

21 potential benefits and then see if the woman

22 could do without, that they would be aware of

23 what the potential risks are, and then

24 consider other strategies as well.

25 Q. What other strategies are there

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1 to treat migraine in pregnancy?

2 A. Well, there are other

3 prescription and nonprescription medicines

4 that can be used for migraine.

5 Q. What would you recommend over

6 acetaminophen, Doctor?

7 A. Well, so this is a key issue

8 here in this particular case. I think one of

9 the things that I find concerning was that

10 mothers were counseled that it was unsafe for

11 them to take nonsteroidal anti-inflammatory

12 medicines such as ibuprofen and aspirin

13 because of the peripheral effects of those

14 medicines. And so they were encouraged to

15 take acetaminophen because acetaminophen

16 didn't have those peripheral effects.

17 The problem is that

18 acetaminophen has central effects, and the

19 central effects were not well-characterized

20 with regards to neurodevelopmental outcome.

21 So that I would inform them

22 about the potential risks for taking

23 acetaminophen during pregnancy, and also in

24 terms of dose and duration. And I would

25 caution about the use of that in situations

<p style="text-align: right;">Page 234</p> <p>1 where it's not essential, and I would 2 consider other alternatives.</p> <p>3 When I reviewed the literature 4 with regards to ibuprofen, I was surprised to 5 see, actually, that the literature is ex -- 6 very modest with regards to the potential 7 risks or outcomes with regards to ibuprofen, 8 for example, with regards to kidney and 9 amniotic fluid and trying to balance the 10 risks and the benefits.</p> <p>11 I would not encourage my 12 patients to not take nonsteroidal and 13 encourage them to take acetaminophen. I 14 would encourage them not to take 15 acetaminophen unless absolutely necessary. 16 For example, for high fever.</p> <p>17 Q. Right.</p> <p>18 And do you remember my 19 question, Doctor? It was what, for your 20 pregnant patients with migraine --</p> <p>21 A. Yeah.</p> <p>22 Q. -- during the pregnancy, what 23 else would you recommend they take other than 24 acetaminophen?</p> <p>25 A. And I would go on to Epocrates,</p>	<p style="text-align: right;">Page 236</p> <p>1 the known risks for acetaminophen. Let's 2 have a discussion and see how this applies to 3 you as an individual.</p> <p>4 Q. Do you know what Epocrates says 5 about acetaminophen right now?</p> <p>6 A. Well, I haven't -- actually, 7 I'm not -- it would be good to take a look at 8 that. You know, as I mentioned before, 9 it's widely assumed by clinicians and 10 patients and their families that 11 acetaminophen is a Category B medicine, but 12 that may not be the case given the labeling, 13 the more recent prescription versions, where 14 it's no longer listed as a Category B.</p> <p>15 Q. You said you were going to go 16 to Epocrates. That was your answer, right?</p> <p>17 A. I -- no, I said that that might 18 be one way that I would look into other 19 alternatives.</p> <p>20 Q. Name one alternative to 21 acetaminophen, other than ibuprofen, for 22 migraine during pregnancy for one of your 23 patients.</p> <p>24 A. There are various prescription 25 medicines for migraine, so -- there are a</p>
<p style="text-align: right;">Page 235</p> <p>1 and then I would look at all of the 2 prescription options. Then I would review 3 the literature, or I would review what 4 category they are, the risks, the benefits 5 for each of those alternatives. And I would 6 also even consider other nonprescription 7 medicines as well.</p> <p>8 And I think that it's important 9 to have a -- you know, an absolute and a 10 relative risk versus benefit for the 11 different medicines and classes of medicines 12 in order to engage in that discussion with 13 patients.</p> <p>14 Q. So you would see what 15 Hippocrates says, the program, right?</p> <p>16 A. Well, I like Epocrates, but --</p> <p>17 Q. Epocrates. You would see what 18 Epocrates says?</p> <p>19 A. Well, that would be one way to 20 explore the other alternatives.</p> <p>21 The other would be to engage in 22 a discussion: Well, all right, so here is 23 the data with ibuprofen, for example. Here 24 are what are the known risks for ibuprofen. 25 Here's the data for acetaminophen. Here are</p>	<p style="text-align: right;">Page 237</p> <p>1 number of prescription medicines for 2 migraine, so I would go on -- I would 3 determine the risks and benefits for those 4 prescription medicines for migraine, and then 5 I would weight it, and then I'd have a 6 discussion with the patient.</p> <p>7 Q. Topiramate is one prescription 8 medication for migraine, correct?</p> <p>9 A. Topiramate is one prescription 10 medicine for migraine.</p> <p>11 Q. Would you give your -- would 12 you recommend your patient take topiramate 13 over acetaminophen during pregnancy for 14 migraine?</p> <p>15 A. No, I don't think that I would 16 go to topiramate as an alternative.</p> <p>17 Q. Okay. It's one of the only 18 medications indicated for migraine, correct?</p> <p>19 A. No. There are other medicines 20 that are also indicated for migraine.</p> <p>21 Q. Not a ton of them, right?</p> <p>22 MR. DOVEL: Objection. Form.</p> <p>23 THE WITNESS: There are a 24 number of prescription medicines, and 25 there are traditional medicines that</p>

<p style="text-align: right;">Page 238</p> <p>1 are used for prophylaxis against</p> <p>2 migraine, so there are several</p> <p>3 alternatives.</p> <p>4 QUESTIONS BY MR. MURDICA:</p> <p>5 Q. You know -- you know some of</p> <p>6 the migraine medications are known</p> <p>7 teratogens, correct?</p> <p>8 MR. DOVEL: I'm not getting</p> <p>9 time to put my objections in here, so</p> <p>10 if you could just give me a chance so</p> <p>11 we don't overlap the court reporter.</p> <p>12 THE WITNESS: Thank you.</p> <p>13 MR. DOVEL: Objection. Form.</p> <p>14 QUESTIONS BY MR. MURDICA:</p> <p>15 Q. You know that some of the</p> <p>16 medications specifically indicated for</p> <p>17 migraine are teratogens, correct?</p> <p>18 A. Well, I do know that. I do</p> <p>19 know, for example, that valproate is a</p> <p>20 classic medicine that actually has</p> <p>21 antimigraine effects and that also is a</p> <p>22 medicine that causes neurodevelopmental</p> <p>23 disorders.</p> <p>24 Q. You said something about</p> <p>25 pregnancy categories earlier.</p>	<p style="text-align: right;">Page 240</p> <p>1 Gynecologists recommend during pregnancy that</p> <p>2 a woman with migraine should, in fact, take</p> <p>3 acetaminophen. As of today, that's the</p> <p>4 recommendation, correct?</p> <p>5 A. That's a mistake.</p> <p>6 Q. Okay. But you know that that's</p> <p>7 the case, and you just disagree with it,</p> <p>8 right?</p> <p>9 A. I disagree with it, and I</p> <p>10 believe that that organization will modify</p> <p>11 those recommendations over time as they</p> <p>12 incorporate epidemiology and animal model</p> <p>13 data.</p> <p>14 Q. Have you, in your practice,</p> <p>15 recommended against the ACOG recommendation</p> <p>16 to any of your patients who were pregnant?</p> <p>17 A. I have recommended to my</p> <p>18 patients who were pregnant or considering</p> <p>19 getting pregnant that they -- that it was not</p> <p>20 safe to use acetaminophen and that they would</p> <p>21 be at increased risk.</p> <p>22 So, yes, I've -- I have not</p> <p>23 adopted their suggestions because I feel that</p> <p>24 that would be potentially harmful to my</p> <p>25 patients.</p>
<p style="text-align: right;">Page 239</p> <p>1 You know, do you not,</p> <p>2 Dr. Hollander, that pregnancy categories were</p> <p>3 abolished in 2015?</p> <p>4 A. I do know that those are --</p> <p>5 well, not active, but I do know that -- and</p> <p>6 they don't necessarily apply to</p> <p>7 over-the-counter medicines as well. But I do</p> <p>8 know that there are warnings with regards to</p> <p>9 pregnancy and lactation for prescription</p> <p>10 medicines.</p> <p>11 Q. Right.</p> <p>12 My question was, you were</p> <p>13 referencing pregnancy categories. You know</p> <p>14 those haven't been used since 2015, correct?</p> <p>15 A. I know that that was modified,</p> <p>16 yes.</p> <p>17 Q. Do you disagree with anything I</p> <p>18 just said? Because you didn't give me a</p> <p>19 clean answer.</p> <p>20 A. Well, I mean, I think even</p> <p>21 before that time they didn't necessarily</p> <p>22 apply to over-the-counter. So they only</p> <p>23 applied to prescription medicines.</p> <p>24 Q. Okay. Doctor, you know that</p> <p>25 the American College of Obstetricians and</p>	<p style="text-align: right;">Page 241</p> <p>1 Q. Okay. Does your practice -- do</p> <p>2 you have a medical practice with other</p> <p>3 doctors?</p> <p>4 A. Yes.</p> <p>5 Q. Okay. Do they know that you're</p> <p>6 recommending against medical organization</p> <p>7 guidelines to your patients?</p> <p>8 A. So, you know, doctors need to</p> <p>9 inform themselves of risks and benefits and</p> <p>10 engage in those kind of discussions with</p> <p>11 their patients. They want accurate</p> <p>12 information.</p> <p>13 Q. All right.</p> <p>14 A. Yeah, so we would turn to</p> <p>15 available information to have a discussion</p> <p>16 with our patients, and we would not just</p> <p>17 adopt a recommendation from an organization,</p> <p>18 particularly if we disagree with it.</p> <p>19 Q. Okay. Right.</p> <p>20 And you didn't come to your</p> <p>21 conclusion about acetaminophen and ASD and</p> <p>22 ADHD until you were paid by plaintiffs'</p> <p>23 lawyers to look at it, correct? This is all</p> <p>24 new?</p> <p>25 MR. DOVEL: Objection. Form.</p>

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1 THE WITNESS: No, that's not
 2 correct. So --
 3 QUESTIONS BY MR. MURDICA:
 4 Q. Okay.
 5 A. -- as I mentioned, I -- after
 6 evaluating all of the data, including
 7 epidemiology data and animal model data, and
 8 what -- and performing a Bradford Hill
 9 analysis, I formed an opinion with regards to
 10 causation.
 11 Q. Right.
 12 A. And then I utilized that
 13 opinion in terms of my discussions with my
 14 patients.
 15 Q. Right.
 16 And that opinion on causation
 17 you just formed when you did Bradford Hill
 18 last month, correct?
 19 A. I did that prior to my initial
 20 report.
 21 Q. Okay. When did you do that?
 22 When did you do the Bradford Hill?
 23 A. Prior to my initial amended
 24 report.
 25 Q. Okay. So prior to June

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1 of 2023?
 2 A. Yes.
 3 Q. Okay. After February of 2023?
 4 A. Yes.
 5 Q. Okay. So between February and
 6 June of 2023, you did your Bradford Hill,
 7 correct?
 8 A. That's correct.
 9 Q. And that's when you first
 10 determined that there was a causal
 11 relationship between acetaminophen and ADHD
 12 and ASD, correct?
 13 A. That's correct.
 14 Q. Okay. We were talking about
 15 Exhibit 52, Masarwa 2018, for quite a while
 16 before the last break.
 17 You remember that discussion?
 18 MR. DOVEL: 52 or 53?
 19 MR. MURDICA: 53. Sorry, 53.
 20 MR. DOVEL: Before we go on, do
 21 you have his documents? Let's --
 22 MS. JOHNSTON: I do, yeah.
 23 QUESTIONS BY MR. MURDICA:
 24 Q. Are you ready to proceed,
 25 Doctor?

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1 A. Yes, I am.
 2 Q. Okay. If you look back at your
 3 amended -- or your rebuttal report on
 4 page 15 --
 5 A. Yes.
 6 Q. -- for me.
 7 Okay. This is how we got onto
 8 the topic of Masarwa.
 9 You see on page 15, Masarwa is
 10 your first listed study where you say
 11 association between APAP exposure and ASD and
 12 ADHD has been found consistently in
 13 meta-analyses and systemic reviews --
 14 systematic reviews, right?
 15 A. Correct.
 16 Q. Okay. Now, I looked through
 17 your report, and I don't see any other
 18 Masarwas.
 19 Is that right?
 20 A. Well, I can take a look and see
 21 if -- you mean --
 22 Q. Well, do you --
 23 A. -- Masarwa in a different year
 24 or --
 25 Q. Yeah. Right.

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1 Do you recall seeing any
 2 other -- in all the work that you did to
 3 prepare for this, do you recall seeing any
 4 other Masarwas?
 5 A. It's possible, but I don't
 6 recall.
 7 Q. Okay. So you don't -- because
 8 I didn't see it in here.
 9 A. Okay.
 10 Q. You don't know that two years
 11 later Masarwa did an analysis on the biases
 12 on --
 13 A. Oh, I'm sorry, I do -- you
 14 know, I do know it, and I did cite it in my
 15 report.
 16 Q. Okay. And what page is that?
 17 A. I cited it on page 24.
 18 Q. Okay. So, Doctor, you know --
 19 on page 24.
 20 Oh, which report are you
 21 looking at?
 22 A. The rebuttal report. It's
 23 under A, Surveys in Lieu of Clinical
 24 Diagnoses.
 25 Q. Your --

<p>Page 246</p> <p>1 A. And then I'm actually citing 2 the Faraone report at 67. 3 Q. Okay. Oh, right. You're 4 quoting Faraone? 5 A. Yeah. 6 Q. Yeah, that's not -- that's a 7 quotation of Faraone's report. 8 A. Right. 9 Q. Okay. So your report -- do you 10 know what Masarwa 2020 says? 11 A. Well, I can -- know what it 12 says as it relates to Faraone quoting that. 13 Q. Right. 14 You didn't go and get it 15 yourself, correct? 16 A. Well, I'm not sure if I -- 17 well, let's take a look at the materials 18 cited list. 19 Yeah, I cited both the 2018 20 study, and I also cited the 2020 study. 21 Q. That's in your list of reliance 22 materials, correct? 23 A. That's right. 24 Q. Right. 25 Do you recall reading it?</p>	<p>Page 248</p> <p>1 you don't -- you don't know what Masarwa 2020 2 says, right? 3 A. Well, the issue at hand is 4 differential versus nondifferential 5 misclassification. So misclassification that 6 affects both cohorts, so in terms of outcome, 7 really doesn't have an effect. So the issue 8 is really whether there's a differential bias 9 or a nondifferential bias. 10 Q. And did you -- did you do that 11 analysis and make that determination with 12 respect to Masarwa 2020? 13 A. Well, I can do that with 14 regards to any study. 15 Q. Right. 16 And did you do that before you 17 rendered your opinions here? 18 A. Well, let's take a look at my 19 rebuttal report here. 20 Q. Let me know what page you're 21 on. 22 A. I'm on page 24. 23 Right. Okay. 24 Q. Okay. So did you do an 25 analysis on Masarwa 2020, and if so, what was</p>
<p>Page 247</p> <p>1 A. Yeah, I recall seeing it. 2 Q. You read everything in your 3 reliance list? 4 A. Yeah, I relied on all this 5 information. 6 Q. I asked you, did you read 7 everything in the reliance list? 8 A. I reviewed it. I didn't read 9 every word in every article, but I did review 10 these articles and incorporate them into my 11 opinion. 12 Q. Okay. So you didn't -- you 13 didn't cite Masarwa 2020 in your opinion; you 14 quoted Dr. Faraone. 15 But my question is this, 16 regardless, Dr. Hollander, do you recall what 17 Masarwa 2020 determined? 18 A. Well, I can -- I can tell you 19 what Faraone was quoting from the Masarwa 20 2020. 21 Q. Well, Dr. Hollander, you quoted 22 that because you disagree with Dr. Faraone, 23 correct? 24 A. I do disagree with Dr. Faraone. 25 Q. Okay. So sitting here today,</p>	<p>Page 249</p> <p>1 your conclusion? 2 A. Well, I did an analysis on all 3 of the available literature with regards to 4 differential and nondifferential 5 misclassification. 6 Q. And misclassification as to 7 what? 8 A. So what Dr. Faraone is 9 contending that Masarwa said is that he's 10 suggesting that caregiver-reported 11 questionnaires could -- or even health care 12 provider diagnoses could somehow have a 13 nondifferential misclassification if the 14 provider knows about the parent's use of 15 acetaminophen. 16 Q. Okay. And you disagree with 17 Dr. Faraone on that, correct? 18 A. Oh, yeah, I do. I do disagree. 19 Q. Okay. And is that why Masarwa 20 2020 is not cited in your statement 21 affirmatively? 22 A. Well, I did mention that it is 23 in my materials relied upon list. 24 Q. Right. Sorry, I'm talking -- 25 I'm talking about your rebuttal report. Your</p>

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1 report.

2 MR. DOVEL: Objection. Form.

3 QUESTIONS BY MR. MURDICA:

4 Q. Dr. Hollander, you didn't --

5 A. Yes.

6 Q. You didn't find Masarwa 2020 to

7 be important enough to cite, correct?

8 And in fact, you disagreed with

9 Dr. Faraone's citation of it?

10 A. Well, I do disagree, yes.

11 Q. Okay. I'm going to mark --

12 A. And I can explain a little bit

13 more about --

14 Q. Go ahead. Explain it, please.

15 A. So that, look, these are cohort

16 studies, right? So you have exposures being

17 assessed at one time point. And then you

18 have a prospective study where then

19 individuals go on to develop the disorder,

20 let's say ADHD, over time, right?

21 The reporting of the diagnosis

22 over time is not influenced by the

23 classification of the exposure, which is

24 systematically assessed for during the

25 pregnancy period, and then there are two

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1 aspects to the follow-up or outcome measure.

2 So one aspect could be

3 utilizing valid and reliable scales. Another

4 way to do that would be to examine medical

5 records for diagnostic codes.

6 Medical records for the

7 diagnostic codes or the well-validated

8 outcome measures that are administered are

9 done without the knowledge of the exposure.

10 So they're not influenced -- so they're

11 independent variable from the exposure

12 variable, both in terms of temporality,

13 because the exposure variable is collected at

14 the time of pregnancy, and the outcome

15 measure is collected over time in this kind

16 of longitudinal kind of follow-up.

17 And then the other point is

18 that there are various ways to kind of get

19 that outcome measure. The outcome measure

20 can be based on validated scales, or the

21 outcome measures could be based on clinical

22 diagnoses.

23 But there's -- that's a --

24 that's a nondifferential classification,

25 because any kind of bias that could happen

Page 252

1 would be independent of the cohort.

2 Q. Dr. Hollander, do you know that

3 Masarwa 2020 determined that unmeasured

4 confounding caused their results in 2018 and

5 it was not a valid correlation?

6 A. Well, I know that unmeasured

7 confounding is always a potential concern.

8 So that means that it's possible that some

9 variable that hasn't been considered is

10 influencing the relationship between the

11 exposure and the outcome, right? So there's

12 un -- unknown variable.

13 There are other ways to deal

14 with that, such as the use of negative

15 controls. So a negative control would take

16 away that as a potential risk because the

17 negative control would be looking at it at

18 the different time points.

19 So you get the same -- if you

20 get the -- if you get the finding in the

21 pregnancy and follow-up time but you don't

22 get it when these -- when the variable is

23 before or after, then that would suggest that

24 the unmeasured confounder -- confounders

25 aren't influencing the relationship.

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1 Q. Dr. Hollander, don't you think

2 it's important that when you're rendering a

3 causation opinion that you consider an

4 author's own determination that their

5 meta-analysis was biased?

6 A. Well, I'd be glad to review

7 that article with you now, but I can tell you

8 that probably the best way to deal with the

9 unmeasured confounders is by using a -- you

10 know, a negative control. That's probably

11 the best way to deal with that.

12 Q. And do you recall Masarwa using

13 a negative control?

14 A. I'm not sure that he did, but

15 there are a number of other examples of the

16 use of negative controls which show that the

17 relationship between exposure and outcome

18 persists even after the negative controls.

19 Q. And I'm -- we're talking about

20 Masarwa, Dr. Hollander.

21 A. Okay.

22 (Hollander Exhibit 55 marked

23 for identification.)

24 QUESTIONS BY MR. MURDICA:

25 Q. Okay?

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1 Let's mark this as Exhibit 55.

2 A. Right.

3 Q. She needs to put a sticker on

4 there.

5 Dr. Hollander, you should now

6 have in front of you what's been marked as

7 Exhibit 55.

8 Do you see it?

9 A. Yes.

10 Q. Okay. Do you see that to be by

11 a Reem Masarwa?

12 A. Yes.

13 Q. Do you see that it's dated

14 2020?

15 A. Yes.

16 Q. Do you recognize this as the

17 same author of Exhibit 53?

18 A. Yes. The same author but a

19 different publication.

20 Q. Okay. And this publication is

21 a bias review of the prior publication,

22 Exhibit 53, correct?

23 A. Yes, they're examining that

24 specific issue.

25 Q. They're examining the specific

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1 findings of Masarwa 2018 for bias, correct?

2 A. Correct.

3 Q. Okay. I'd like you to turn to

4 the final page.

5 And by the way, do you recall

6 reading this before today?

7 A. I have seen it before.

8 Q. Okay. So to the extent it's

9 not in your report, that was a choice you

10 made, right?

11 MR. DOVEL: Objection.

12 Foundation.

13 THE WITNESS: I mean, again, I

14 see it in -- in my -- it's mentioned

15 in my rebuttal report and in materials

16 considered.

17 QUESTIONS BY MR. MURDICA:

18 Q. In your rebuttal report, it's a

19 quotation from Dr. Faraone's report, right?

20 A. Correct.

21 Q. Okay. So my question was, to

22 the extent this is not in your report, that

23 you didn't raise it, that was a choice. You

24 reviewed this before you rendered your

25 report, correct?

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1 MR. DOVEL: Objection. Form.

2 QUESTIONS BY MR. MURDICA:

3 Q. Can you answer my question,

4 Doctor?

5 A. I'm trying to -- well, I'm

6 saying that it is addressed in the rebuttal

7 report.

8 Q. Okay.

9 A. In fact, I respond to this in

10 the rebuttal report.

11 Q. Whatever you included or didn't

12 include in your report was a choice, because

13 your testimony is that you reviewed this

14 before your report, correct?

15 A. Yes.

16 Q. Okay. Turn to page 316,

17 conclusions, please.

18 A. Uh-huh.

19 Q. First sentence. "The observed

20 association between acetaminophen use during

21 pregnancy and increased risk for ADHD in the

22 offspring is likely the result of bias. This

23 systematic error appears to be predominantly

24 driven by unmeasured confounding and exposure

25 misclassification."

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1 Did I read that correctly?

2 A. You read it correctly.

3 Q. So you, Dr. Hollander, knew

4 that the authors made this conclusion and

5 just testified for an hour about how

6 important and how strong Exhibit 53, Masarwa

7 2018, is, correct?

8 MR. DOVEL: Objection. Form.

9 THE WITNESS: Well, I did

10 mention that the Masarwa study was

11 strong, and I also addressed the issue

12 here of what -- the unmeasured

13 confounders.

14 QUESTIONS BY MR. MURDICA:

15 Q. So to -- for Dr. Hollander,

16 Exhibit 55 doesn't change any of the opinions

17 and testimony you offered about Exhibit 53;

18 is that fair?

19 A. I think it doesn't change my

20 opinions, and the reason for that is that

21 the -- this issue has been addressed by the

22 use of the negative exposures. You can --

23 you can take that into account by doing that

24 other way to assess it.

25 Q. Dr. Hollander, I'm asking you

Page 258

1 about Masarwa 2018.

2 A. Right.

3 Q. You testified at length about

4 Masarwa 2018 and its importance to your

5 opinions, and my question is this,

6 Dr. Hollander.

7 A. Right.

8 Q. You considered what's in front

9 of you, Masarwa 2020, before you offered that

10 testimony, correct?

11 A. That's right.

12 Q. Okay. Do you -- you can see

13 that these authors are from Montreal,

14 primarily from McGill University.

15 Are you familiar with that

16 institution?

17 A. Yes, I am.

18 Q. Do you have any reason to

19 criticize the authors or their institution?

20 A. No. I think that's a strong

21 institution.

22 Q. Okay. I'm going to mark -- by

23 the way, is the -- are the supplemental

24 materials to Masarwa 2020 listed on your

25 reliance list?

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1 A. Well, it looks to me like

2 pages 309 to 317 are listed in my materials

3 considered --

4 Q. Okay.

5 A. -- list.

6 Q. So as far as you know, you did

7 not go and look at the supplemental materials

8 for Exhibit 55, correct?

9 A. I'd be happy to look at them

10 now if you --

11 Q. Okay. And that's fairly common

12 for studies like this, that the authors, so

13 that they don't clog up the journal space,

14 they provide their data in supplemental

15 tables you can get online, right?

16 A. Well, there are different

17 reasons to put material -- list supplemental

18 material. You know, one is there are

19 other -- it's material that sort of provides

20 additional evidence from the study but

21 doesn't directly relate to the question, you

22 know, at hand, so it's not critical. There's

23 always an issue in terms of reducing the

24 space of the number of articles. So --

25 Q. But at --

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1 A. -- you know, material is put in

2 supplemental material sometimes because it's

3 not part of the specific primary question

4 being tested.

5 Q. And my only point, Doctor, if

6 you -- would you agree with me that it's

7 fairly common to have supplemental

8 materials --

9 A. Yeah.

10 Q. -- for publications?

11 A. I would agree.

12 (Hollander Exhibit 56 marked

13 for identification.)

14 QUESTIONS BY MR. MURDICA:

15 Q. Okay. Let's mark this as

16 Exhibit 56.

17 Doctor, you now have in front

18 of you what's been marked as Exhibit 56.

19 Do you see it?

20 A. Yes.

21 Q. Okay. Do you agree that you

22 haven't seen this before today?

23 A. This comes from the

24 supplemental material from this --

25 Q. Yeah, my --

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1 A. -- 20 --

2 Q. I'm making a representation to

3 you, and if you did the comparison of what's

4 studied, I'm sure you can -- you could agree

5 with me. But my representation to you is

6 this is the supplemental tables for Masarwa

7 2020.

8 A. Uh-huh. Let me take a look.

9 Q. Doctor, the question that was

10 pending is whether you believe you've ever

11 seen this before.

12 A. I don't know whether I've -- I

13 don't think I've reviewed this in detail.

14 Q. Okay. I'd like to direct you

15 to the fourth page.

16 Do you see E-Figure 2, Doctor?

17 A. E Table 2?

18 Q. E-Figure 2. Go one more. Go

19 one or two more pages. One more page from

20 there. Right in front of you. E-Figure 2.

21 A. Okay.

22 Q. It's titled "Unadjusted Advised

23 Corrected Risk Ratios for Unmeasured

24 Confounding Parental ADHD."

25 Do you see that?

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1 A. Yes.

2 Q. Okay. So do you see the little

3 chart?

4 A. Yes.

5 Q. And we know you like -- we know

6 you like charts because you were talking

7 about the JJCI plots before, right?

8 A. Well, I do like visual figures

9 that represent the data, yes.

10 Q. And so you see what happens

11 when Masarwa went and corrected for the

12 parental ADHD, which is a marker of the

13 genetic influence of ADHD, the correlation

14 disappeared.

15 And you see the -- you see the

16 asterisk way below the dots, unadjusted and

17 biased corrected?

18 A. Well, I would disagree with one

19 component that you said, again, which is that

20 you said the parental ADHD represents the

21 genetics. So I don't agree with that. That

22 represents the familial, right?

23 Q. Okay. Doctor, if you match up

24 Exhibit 56 with Exhibit 55, you will see that

25 the parental ADHD influence, when corrected,

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1 was the bias that caused the results in

2 Masarwa 2018 that you were very excited

3 about.

4 Do you see that change in

5 E-Figure 2 on Exhibit 56?

6 A. Well, I see E-Figure 2 in

7 Exhibit 56, and I see that they have the

8 unadjusted. And then what they're trying to

9 do is deal with one unmeasured confound,

10 which is parental ADHD, right? And so they

11 have the unadjusted, and then they have the

12 bias corrected.

13 And I see that for one, two,

14 three, four, five studies, when you correct

15 it, the risk ratio goes down somewhat. And

16 then I see in two studies it doesn't go down,

17 or it -- or it goes up.

18 Q. And do you see, Doctor,

19 number 2, the second study? That's Liew,

20 right? That was the very large cohort study.

21 That was what was driving the meta-analysis.

22 Do you recall that?

23 MR. DOVEL: Objection. Form.

24 THE WITNESS: Well, let's take

25 a look and see if that was what was

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1 driving it. In order to make any

2 statement about that, I need to go

3 back.

4 Can I have the --

5 QUESTIONS BY MR. MURDICA:

6 Q. Sure, Doctor.

7 A. -- the original?

8 Q. I thought you had it in front

9 of you.

10 A. Oh, here we go.

11 Well, I don't really see that,

12 to tell you the truth. So I'm looking at --

13 I guess you're referring to Figure 2 because

14 this is the risk ratio for these six cohorts

15 for attention-deficit/hyperactivity disorder,

16 right?

17 And I'm looking at the Liew

18 article, and I'm looking at -- no, I mean,

19 that's not driving the -- it's right in the

20 middle of the overall. So that's not one of

21 the studies that has the higher relative risk

22 and is driving the overall risk ratio.

23 Q. Dr. Hollander, is that -- your

24 belief is that what drives a meta-analysis is

25 the risk ratio? And that's what drives a

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1 study's influence on the meta-analysis, not

2 the number of participants?

3 A. No, I think -- well, they both

4 can influence it. So it's both --

5 Q. Right.

6 A. -- the sample size and the risk

7 ratio.

8 Q. Right.

9 And we're going to look at

10 other meta-analyses and --

11 A. Yeah, but you're -- what you're

12 saying is just not right. If you look at it,

13 the Liew -- so -- all right. So when you --

14 Q. That's --

15 A. -- correct for unmeasured

16 confounding, which is parental ADHD in

17 number 2, which is the Liew, and then you

18 look at it here, the Liew study is actually,

19 if anything, pulling the overall risk ratio

20 down rather than driving it up. Because it's

21 somewhat below that.

22 Q. It's your belief,

23 Dr. Hollander, that each of the risk ratios

24 is considered equally and they're just

25 averaged, right?

<p style="text-align: right;">Page 266</p> <p>1 A. No.</p> <p>2 Q. Okay.</p> <p>3 A. No. I think you're right, and</p> <p>4 so sample size plays a role.</p> <p>5 Q. Okay. Well, you just said I'm</p> <p>6 wrong, now you're saying I'm right. So you</p> <p>7 need to pick one.</p> <p>8 A. Well, if you look at the --</p> <p>9 look at the risk ratio.</p> <p>10 MR. DOVEL: Just let me insert</p> <p>11 an objection.</p> <p>12 THE WITNESS: Yeah.</p> <p>13 MR. DOVEL: That question --</p> <p>14 are you sure you want that question to</p> <p>15 stand? I mean, it's unintelligible.</p> <p>16 You can respond.</p> <p>17 QUESTIONS BY MR. MURDICA:</p> <p>18 Q. Dr. Hollander, it is not your</p> <p>19 testimony that a meta-analysis is done by</p> <p>20 averaging the point estimates of the studies</p> <p>21 in a meta-analysis, correct?</p> <p>22 A. That's correct.</p> <p>23 Q. Okay. Because it's a</p> <p>24 combination influenced by the number -- the</p> <p>25 N, the number of participants in the study,</p>	<p style="text-align: right;">Page 268</p> <p>1 understand that if the largest study is</p> <p>2 attenuated --</p> <p>3 A. Uh-huh.</p> <p>4 Q. -- by parental ADHD, that could</p> <p>5 take away, and in fact did take away, the</p> <p>6 statistical significance of the meta-analysis</p> <p>7 overall? And the point estimate for that</p> <p>8 individual study doesn't matter.</p> <p>9 MR. DOVEL: Objection. Form.</p> <p>10 THE WITNESS: No. Again, I</p> <p>11 disagree because --</p> <p>12 QUESTIONS BY MR. MURDICA:</p> <p>13 Q. Okay. If you don't understand</p> <p>14 it, that's fine.</p> <p>15 MR. DOVEL: The witness was</p> <p>16 responding.</p> <p>17 MR. MURDICA: I just want to</p> <p>18 get it on the record.</p> <p>19 MR. DOVEL: You cut him off.</p> <p>20 I'd appreciate if you let him finish</p> <p>21 his answer.</p> <p>22 THE WITNESS: I think that you</p> <p>23 were making the statement that the</p> <p>24 overall risk ratio was biased because</p> <p>25 of this unmeasured confounder,</p>
<p style="text-align: right;">Page 267</p> <p>1 along with the risk -- with the risk ratio</p> <p>2 that determines the ultimate point estimate</p> <p>3 in the meta-analysis, correct?</p> <p>4 A. That's correct. But if you</p> <p>5 look at the risk ratio or the point estimate</p> <p>6 and the confidence intervals, it doesn't</p> <p>7 matter how -- if anything, if it's larger or</p> <p>8 smaller, it's actually dragging the risk</p> <p>9 ratio down rather than pulling it up.</p> <p>10 Q. Okay.</p> <p>11 A. So it -- but I'm responding to</p> <p>12 your comment, which it was the -- you said</p> <p>13 that the Liew study was what was dragging the</p> <p>14 risk ratio up, and that's just not the case.</p> <p>15 Q. I didn't say -- okay, Doctor,</p> <p>16 I -- the meta-analysis in 2018 determined</p> <p>17 that it was positive and statistically</p> <p>18 significant, correct?</p> <p>19 Overall, the meta-analysis</p> <p>20 conclusion found a positive and statistically</p> <p>21 significant association, correct?</p> <p>22 A. Well, that's correct. And also</p> <p>23 a relationship between, you know, age at</p> <p>24 follow-up and exposure, yeah.</p> <p>25 Q. So, Dr. Hollander, do you not</p>	<p style="text-align: right;">Page 269</p> <p>1 parental ADHD, and it was the Liew</p> <p>2 study, number 2, that accounted for</p> <p>3 that.</p> <p>4 But I'm telling you based on</p> <p>5 Figure 2 that the -- if you look at</p> <p>6 it, the relative risk for the Liew</p> <p>7 study is only 1.29.</p> <p>8 QUESTIONS BY MR. MURDICA:</p> <p>9 Q. Okay.</p> <p>10 A. Whereas the relative risk for</p> <p>11 the Streissguth study and the Thompson study</p> <p>12 and the Stergiakouli study are all well above</p> <p>13 that.</p> <p>14 So I disagree that that's</p> <p>15 what's -- I disagree that this impact on the</p> <p>16 Liew study is what is driving the elevated</p> <p>17 relative risk here.</p> <p>18 Q. Okay. And, Doctor,</p> <p>19 respectfully, we're not talking about the</p> <p>20 relative risk. We're talking about the</p> <p>21 statistically significant findings in the</p> <p>22 meta-analysis.</p> <p>23 Do you understand that?</p> <p>24 A. Okay. That's a different</p> <p>25 issue.</p>

<p style="text-align: right;">Page 270</p> <p>1 Q. Right. Okay.</p> <p>2 So understanding that issue --</p> <p>3 A. Okay.</p> <p>4 Q. -- do you understand that the</p> <p>5 Liew study being confounded by parental ADHD</p> <p>6 could undo the positive finding in the</p> <p>7 meta-analysis that was statistically</p> <p>8 significant?</p> <p>9 A. I understand that.</p> <p>10 Q. Okay. Do you have any basis to</p> <p>11 disagree between Exhibit 55 and 56 that</p> <p>12 that's what -- whether you -- that that's</p> <p>13 what Masarwa determined?</p> <p>14 A. Well, first of all, you know,</p> <p>15 again, I'm getting back to -- even if you're</p> <p>16 looking at the adjusted versus the</p> <p>17 uncorrected, the risk ratio is still in the</p> <p>18 same direction throughout. So it's still a</p> <p>19 positive relationship, whether it's</p> <p>20 unadjusted or whether it's bias corrected.</p> <p>21 Q. And your testimony on that,</p> <p>22 Dr. Hollander, you're saying it's still</p> <p>23 positive, but it's not statistically</p> <p>24 significant, correct?</p> <p>25 A. Yeah, the -- you still have a</p>	<p style="text-align: right;">Page 272</p> <p>1 study was biased, and that's why they found a</p> <p>2 statistically significant correlation?</p> <p>3 A. Well, I do agree that when they</p> <p>4 adjust for this unmeasured confounder,</p> <p>5 there -- the risk ratios are lower.</p> <p>6 Q. Okay. And the reason you chose</p> <p>7 not to explain that in your report is what?</p> <p>8 A. Because I also talk about other</p> <p>9 ways to deal with unmeasured confounders for</p> <p>10 parental effects.</p> <p>11 Q. Okay. So it was a choice,</p> <p>12 that when you cited Masarwa 2018, to not</p> <p>13 include Masarwa 2020 right after that with a</p> <p>14 footnote that said, but this effect</p> <p>15 disappeared when accounting for bias, right?</p> <p>16 A. Well --</p> <p>17 MR. DOVEL: Objection. Form.</p> <p>18 THE WITNESS: I'm not -- I</p> <p>19 would say that it's -- when you --</p> <p>20 when you adjust for it, the findings</p> <p>21 are less robust but continued to have</p> <p>22 a positive association.</p> <p>23 QUESTIONS BY MR. MURDICA:</p> <p>24 Q. Right.</p> <p>25 But you didn't put that in your</p>
<p style="text-align: right;">Page 271</p> <p>1 positive association throughout all of the</p> <p>2 studies.</p> <p>3 Q. Okay.</p> <p>4 A. The other thing I would say,</p> <p>5 again, is that there are then other ways to</p> <p>6 deal with this issue of unmeasured</p> <p>7 confounders or parental illness.</p> <p>8 Q. Do you --</p> <p>9 A. So that this is -- I guess this</p> <p>10 is one way to deal with that.</p> <p>11 But I think that what I've said</p> <p>12 also is that there are other approaches that</p> <p>13 can deal with these unmeasured confounders</p> <p>14 where the relationship between exposure and</p> <p>15 outcome persists.</p> <p>16 Q. Okay. And we're still talking</p> <p>17 about Masarwa. I understand your testimony.</p> <p>18 A. Okay.</p> <p>19 Q. So let me ask two more</p> <p>20 questions --</p> <p>21 A. Okay.</p> <p>22 Q. -- on Masarwa.</p> <p>23 A. All right.</p> <p>24 Q. Do you disagree with the</p> <p>25 author's own determination that their 2018</p>	<p style="text-align: right;">Page 273</p> <p>1 report, correct?</p> <p>2 A. I didn't put that in my report.</p> <p>3 Q. Okay. Let's go to page 15,</p> <p>4 please, of your amended report. I'm sorry,</p> <p>5 12.</p> <p>6 All right. Are you on page 12</p> <p>7 of your supplemental report, Doctor?</p> <p>8 A. My rebuttal --</p> <p>9 Q. Sorry, your -- I apologize.</p> <p>10 A. -- or my initial report?</p> <p>11 Q. Your rebuttal report.</p> <p>12 A. Okay.</p> <p>13 Q. I led you astray there. My</p> <p>14 apologies.</p> <p>15 A. Okay. Okay.</p> <p>16 Q. Okay. Do you remember I asked</p> <p>17 you some questions about Alemany --</p> <p>18 A. Yes.</p> <p>19 Q. -- which is listed on page 12?</p> <p>20 And then, in fact, if you turn</p> <p>21 to page 15, which we were just discussing</p> <p>22 about Masarwa, you'll see that you list</p> <p>23 Alemany as another consistent meta-analysis</p> <p>24 along with Masarwa?</p> <p>25 A. I see that on page 15, that --</p>

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1 Q. Yes.

2 A. -- Alemany is listed along with

3 Masarwa.

4 Q. Right.

5 And you relied on Alemany on

6 page 12 as well because it was an

7 exceptionally large group of participants

8 according to you, right?

9 A. Let's take a look because --

10 Q. Sure.

11 A. Well, not only that it was a

12 large group of participants, 73,000

13 mother-child pairs, but also that it was data

14 from six different European population-based

15 birth cohorts, yeah.

16 Q. Okay. So we're going to mark

17 this in a second, but when is the last time

18 you looked at the Alemany study?

19 A. I don't -- well, I don't have

20 a -- I'm not sure. I know that I looked at

21 it prior to preparing my rebuttal, but I

22 can't recall if I looked at it after that

23 time.

24 Q. Okay. Did you look at these

25 studies in preparation for your testimony

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1 today? Or was the -- your rebuttal report

2 the last time you looked at them?

3 A. No. I looked at some of these

4 studies prior to this. I'm not sure that I

5 looked at all of them prior to this.

6 Q. Okay. We're going to mark this

7 as Exhibit 57.

8 MR. MURDICA: My colleague

9 tells me we've been going about an

10 hour. This next study is going to

11 take a while.

12 Do you want to take a

13 five-minute break now?

14 MR. DOVEL: Yeah, let's take

15 ten minutes?

16 MR. MURDICA: Okay.

17 VIDEOGRAPHER: The time is

18 3:38 p.m. We are off the record.

19 (Off the record at 3:38 p.m.)

20 VIDEOGRAPHER: The time right

21 now is 3:54 p.m. We are back on the

22 record.

23 (Hollander Exhibit 57 marked

24 for identification.)

25

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1 QUESTIONS BY MR. MURDICA:

2 Q. Dr. Hollander, are you ready to

3 proceed?

4 A. Yes, I am.

5 Q. Okay. We just marked

6 Exhibit 57, and I'm going to ask you

7 questions about that in a second.

8 In the middle of the last

9 session, we handed you back the charts that

10 Dr. Baccarelli did on the article summaries,

11 and that now has an exhibit marker on it.

12 And it should say 54 -- well, there's

13 probably a copy that's 54.

14 Here is my question.

15 Exhibit 54, Dr. Hollander, is really -- it's

16 really two documents, right? One document is

17 a -- or three. One document is ASD studies,

18 one is ADHD, and one is other?

19 A. That's correct.

20 Q. Okay. And if you look at the

21 first document, the -- at the -- well, I

22 don't know if it's the first. If you look at

23 the ASD document --

24 A. Okay.

25 Q. -- there is, what, five or six

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1 studies on it?

2 A. Yes.

3 Q. Okay. And if you look at the

4 ADHD document, there's more, right?

5 A. 16, I think.

6 Q. Okay. Somewhere in the order

7 of 16.

8 And back to the ASD. Of the --

9 of the six, one of them is Alemany, which is

10 the meta-analysis, Exhibit 57, that we're

11 about to look at, right?

12 A. Yes.

13 Q. Okay. All right. You can put

14 that back aside.

15 And to your knowledge, I assume

16 you trusted Dr. Baccarelli did a good job

17 identifying the studies that are relevant to

18 acetaminophen and ASD and acetaminophen and

19 ADHD, correct?

20 A. Yes, he did.

21 Q. Okay. So you don't have -- you

22 don't have any dispute with the studies that

23 he included on those charts, right?

24 A. No.

25 Q. Okay. Back to Exhibit 57.

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1 This is one of the -- this is
 2 the meta-analysis, right?
 3 A. Yes. It's a meta-analysis of
 4 six different cohorts.
 5 Q. Okay. And this is -- the
 6 outcome here is ASD and ADHD, right?
 7 A. Correct.
 8 Q. All right. And this is
 9 Alemany, which you've cited in your report a
 10 couple times, right?
 11 A. That's correct.
 12 Q. Okay. And the first sentence
 13 of the abstract is that "The potential
 14 etiologic role of early acetaminophen
 15 exposure on ASD and ADHD is inconclusive."
 16 Correct?
 17 A. That's what the first sentence
 18 says.
 19 Q. Okay. And what's the date of
 20 this?
 21 A. 2021.
 22 Q. Okay. Do you disagree with
 23 that statement that Alemany made for this
 24 meta-analysis as of 2021?
 25 MR. DOVEL: Objection. Form.

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1 THE WITNESS: Well, I believe
 2 that prior to 2021 there was lots of
 3 both epidemiology evidence and both
 4 animal model evidence to inform
 5 causation.
 6 QUESTIONS BY MR. MURDICA:
 7 Q. Okay.
 8 A. But I agree with you that
 9 that's what the first sentence says.
 10 Q. Right.
 11 So sitting here today,
 12 Dr. Hollander, do you know more than these
 13 researchers who actually do research on
 14 acetaminophen knew in 2021?
 15 MR. DOVEL: Objection. Form.
 16 THE WITNESS: Well, one
 17 advantage that I have is I've been
 18 able to look at data that included not
 19 only epidemiology data but also animal
 20 model data. And I don't believe that
 21 Alemany, with other authors of
 22 epidemiology studies, looked into the
 23 animal model data and/or the plausible
 24 biological mechanism issues.
 25

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1 QUESTIONS BY MR. MURDICA:
 2 Q. Okay. And did you contact any
 3 of the authors of any of these studies that
 4 you're relying on, or that Dr. Baccarelli is
 5 relying on, to discuss that?
 6 A. I haven't had conversations
 7 with the authors of these studies.
 8 Q. Okay. Have you attempted to
 9 reach out to any of them?
 10 A. No, I haven't attempted --
 11 Q. Okay.
 12 A. -- to reach out to the authors
 13 of any of these studies.
 14 Q. So whether or not they looked
 15 at potential mechanisms or animal data is --
 16 would be complete supposition on your part,
 17 correct?
 18 A. Well, I would say that they
 19 don't -- they don't discuss it, so they
 20 don't -- they do not discuss the epidemiology
 21 findings within the context of either the
 22 plausible biological mechanisms or animal
 23 model data.
 24 Q. You're pretty sure about that?
 25 A. Well, I don't recall seeing

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1 that. Well, actually, no. Let me -- I'm
 2 sorry, let me modify what I said, because
 3 even in this article they do -- they do refer
 4 to plausible biological mechanisms, including
 5 the endocannabinoid system and BDNF and
 6 oxidative stress --
 7 Q. So --
 8 A. -- and endocrine disruptors.
 9 Q. So when you just testified that
 10 they didn't look at potential mechanisms or
 11 animal models, that was not based on fact,
 12 correct?
 13 MR. DOVEL: Objection. Form.
 14 THE WITNESS: Well, I would say
 15 that these authors did include a
 16 discussion of the plausible biological
 17 mechanisms within their discussion.
 18 QUESTIONS BY MR. MURDICA:
 19 Q. Right. So back to my original
 20 question, which was on the first sentence of
 21 the abstract.
 22 Do you, Dr. Hollander, are you
 23 sitting here saying you know more than they
 24 did in 2021 to gauge the available data to
 25 say that they're wrong, that it's

<p style="text-align: right;">Page 282</p> <p>1 inconclusive when they write this at this 2 point? 3 A. Well -- 4 MR. DOVEL: Objection -- let me 5 just get my objection. 6 Objection. Form. 7 THE WITNESS: Okay. So, I 8 mean, if you look at the structure of 9 the abstract, they're -- essentially 10 the first sentence is setting up the 11 issue, and then they discuss the aim. 12 So they're setting up the 13 issue, well, what's the etiologic 14 role? And then to address that, we 15 aim the study. 16 So I think it's providing a 17 little bit of context and then talking 18 about the aims. 19 QUESTIONS BY MR. MURDICA: 20 Q. Right. 21 A. I don't think that the first 22 sentence is a definitive conclusion. 23 Q. I agree. 24 In fact, it says -- 25 Dr. Hollander, it says it's inconclusive,</p>	<p style="text-align: right;">Page 284</p> <p>1 asking about the first sentence, which says, 2 "The potential etiologic role is 3 inconclusive." That was the first sentence 4 of their abstract. 5 So when they set out on this, 6 do you doubt that they believed that when 7 they set upon doing this work? 8 A. Well, I'm suggesting that 9 they're using the initial sentence as an 10 introduction to introduce why would it be 11 valuable to do the study. And then I -- 12 Q. Right. 13 A. Then what their beliefs are, I 14 think, are captured in the last sentence. 15 Q. Right. 16 Doctor, do you have any doubt 17 that when they wrote the first sentence, they 18 didn't mean what they said? 19 MR. DOVEL: Objection. Form. 20 THE WITNESS: I don't know 21 whether they meant what they said. 22 QUESTIONS BY MR. MURDICA: 23 Q. Okay. 24 A. I think that they were 25 introducing a reason why this would be a</p>
<p style="text-align: right;">Page 283</p> <p>1 correct? 2 A. Well, even -- I think that 3 their statement about it being inconclusive 4 is not a definitive statement -- 5 Q. Okay. 6 A. -- because it's introducing the 7 issue. 8 Q. So sitting here in 2023, 9 Dr. Hollander is interpreting what they could 10 have meant in plain writing in 2021, correct? 11 MR. DOVEL: Objection. Form. 12 THE WITNESS: Well, if you look 13 at the last -- so that's the first 14 sentence in the abstract. 15 And then I would direct you to 16 the last sentence in the abstract, 17 which says, "These results replicate 18 previous work and support providing 19 clear information to pregnant women 20 and their partners about potential 21 long-term risks of acetaminophen use." 22 So that's their conclusion. 23 QUESTIONS BY MR. MURDICA: 24 Q. Right. 25 Dr. Hollander, I was just</p>	<p style="text-align: right;">Page 285</p> <p>1 valuable study. 2 I think they were trying to 3 provide some rationale to both the readers 4 and to the editors of the journal on why this 5 article might be of interest. 6 Q. And when is the last time you 7 reviewed this one? 8 A. I think I last reviewed this 9 prior to my -- I think prior to my initial 10 expert report. 11 Q. Okay. So it's been a month and 12 a half since you last looked at it? 13 A. It's possible. 14 Q. Did you look at the 15 supplemental materials for this study? 16 A. I don't recall. 17 Q. Okay. And you see that this 18 analyzes the cohorts that existed at the time 19 in 2021, right? 20 A. Yes. And, I mean, it looks 21 like it analyzed these cohorts from, you 22 know, starting -- that were collected between 23 1991 and 2008. 24 Q. And one of the things they 25 looked at -- you're familiar with the DNBC,</p>

<p style="text-align: right;">Page 286</p> <p>1 right?</p> <p>2 A. Yes, I am.</p> <p>3 Q. And what does that stand for?</p> <p>4 A. It's the Danish National Birth</p> <p>5 Cohort, I believe.</p> <p>6 Q. Right.</p> <p>7 And who studied that?</p> <p>8 A. Let's see. There have been --</p> <p>9 there have been more than one publication</p> <p>10 resulting from that cohort --</p> <p>11 Q. There have.</p> <p>12 A. -- so...</p> <p>13 Q. All right. So you're looking</p> <p>14 back at Exhibit 54 --</p> <p>15 A. I'm looking at the summary --</p> <p>16 Q. -- Dr. Baccarelli's chart?</p> <p>17 A. Yeah. I mean, I could get to</p> <p>18 it, if you like, by going through my report,</p> <p>19 which tells, you know, which cohorts as well.</p> <p>20 Q. Well --</p> <p>21 A. But there are -- there's more</p> <p>22 than one publication that utilized that.</p> <p>23 Q. One of --</p> <p>24 A. Well, here it is in my report,</p> <p>25 actually.</p>	<p style="text-align: right;">Page 288</p> <p>1 they can look by hospital diagnosis, right?</p> <p>2 A. That's correct.</p> <p>3 Q. Because with the exception of</p> <p>4 the DNBC, all of the other cohorts were done</p> <p>5 by report. Report by the mother or family or</p> <p>6 something like that, right?</p> <p>7 A. Well, that is an advantage of</p> <p>8 that particular national birth cohort, yeah.</p> <p>9 Q. Okay. And did you -- did you</p> <p>10 look what happened to the effect when they</p> <p>11 checked the DNBC versus hospital diagnosis</p> <p>12 instead of just maternal report?</p> <p>13 A. Are you referring to the</p> <p>14 Alemany paper, or are you --</p> <p>15 Q. Yeah, I'm talking about</p> <p>16 Alemany, yeah.</p> <p>17 A. Okay. Well, so let's -- if you</p> <p>18 like, we can examine that.</p> <p>19 Q. Yeah, I can help you. It's on</p> <p>20 page 998.</p> <p>21 A. Okay.</p> <p>22 Q. Let the record reflect that</p> <p>23 Dr. Hollander is looking at Dr. Baccarelli's</p> <p>24 exhibit summary and not Exhibit 57.</p> <p>25 MR. DOVEL: That is a false</p>
<p style="text-align: right;">Page 287</p> <p>1 Well, yeah, I talk all about</p> <p>2 this. I mean, it's one of the world's</p> <p>3 largest birth cohorts.</p> <p>4 Q. Right.</p> <p>5 But you've allegedly taken and</p> <p>6 done an expert analysis here, and you can't</p> <p>7 tell us who did the studies on the Danish</p> <p>8 National Birth Cohort?</p> <p>9 MR. DOVEL: Objection. Form.</p> <p>10 THE WITNESS: Well, I can. I'd</p> <p>11 be glad to --</p> <p>12 QUESTIONS BY MR. MURDICA:</p> <p>13 Q. But you don't know it off the</p> <p>14 top of your head?</p> <p>15 A. I can take a look at my report,</p> <p>16 and I can take a look at my summary tables</p> <p>17 here.</p> <p>18 Q. Okay. The summary tables that</p> <p>19 Dr. Baccarelli did? Exhibit 54?</p> <p>20 A. That he summarized aspects of</p> <p>21 different studies, yeah.</p> <p>22 Q. All right. Don't worry about</p> <p>23 it. I'll ask you something else.</p> <p>24 One of the advantages of the</p> <p>25 DNBC is that they also can check and see --</p>	<p style="text-align: right;">Page 289</p> <p>1 statement, and I'd like the examiner</p> <p>2 to withdraw that statement.</p> <p>3 THE WITNESS: Yeah, I'm</p> <p>4 looking --</p> <p>5 MR. MURDICA: Oh, I'm sorry,</p> <p>6 he's looking at both. I apologize. I</p> <p>7 thought you were looking at the --</p> <p>8 MR. DOVEL: He's not looking at</p> <p>9 both. I'd still like you to correct</p> <p>10 your statement.</p> <p>11 MR. MURDICA: Okay. Well, I</p> <p>12 don't know what you were looking at</p> <p>13 then. You were looking at</p> <p>14 Exhibit 57 --</p> <p>15 MR. DOVEL: If you don't know</p> <p>16 what he's looking at, don't put it on</p> <p>17 the record, sir.</p> <p>18 MR. MURDICA: Okay. I believe</p> <p>19 he was looking at Exhibit 54.</p> <p>20 THE WITNESS: Well --</p> <p>21 MR. MURDICA: They were on top</p> <p>22 of each other.</p> <p>23 THE WITNESS: No, you asked me</p> <p>24 to examine the Alemany.</p> <p>25</p>

<p style="text-align: right;">Page 290</p> <p>1 QUESTIONS BY MR. MURDICA:</p> <p>2 Q. I am. That's what I'd like you</p> <p>3 to look at. Page 998 will give you the</p> <p>4 answer, but you can look at whatever you want</p> <p>5 to.</p> <p>6 A. Okay.</p> <p>7 So I'm not sure whether or not</p> <p>8 your -- well, let's take a look at this one.</p> <p>9 Hang on a second.</p> <p>10 Well, so they examined the</p> <p>11 results, and they look at this, you know,</p> <p>12 both with the DNBC and then without the DNBC,</p> <p>13 without the hospital diagnosis. And they</p> <p>14 look at, I guess, the odds ratios in boys and</p> <p>15 girls, with and without that cohort.</p> <p>16 Q. Okay. You understand that the</p> <p>17 first analysis was the DNBC by maternal</p> <p>18 report, and then it was verified in a second</p> <p>19 analysis by hospital report, hospital</p> <p>20 diagnosis, correct?</p> <p>21 A. That's correct.</p> <p>22 Q. Okay. And when they did the</p> <p>23 hospital diagnosis, the statistically</p> <p>24 significant result disappeared, correct?</p> <p>25 A. I'm not sure that that's what</p>	<p style="text-align: right;">Page 292</p> <p>1 A. Yeah.</p> <p>2 Q. You see when they did the</p> <p>3 hospital diagnosis, the statistical</p> <p>4 significance of the effect in boys and girls</p> <p>5 disappeared, correct?</p> <p>6 A. Well, I mean, the first</p> <p>7 statement that they're saying is -- so</p> <p>8 children exposed to acetaminophen were</p> <p>9 19 percent more likely to have ASC symptoms</p> <p>10 within the borderline or clinical range than</p> <p>11 nonexposed. So increased odds ratio.</p> <p>12 And then they get similar</p> <p>13 results using the hospital diagnosis.</p> <p>14 Q. Okay. And then when they</p> <p>15 stratify by sex --</p> <p>16 A. Right.</p> <p>17 Q. -- using the hospital</p> <p>18 diagnosis, neither sex is statistically</p> <p>19 significant, correct?</p> <p>20 A. Well, no. When they -- so</p> <p>21 stratifying by sex, prenatal acetaminophen</p> <p>22 was associated with ASC symptoms among boys,</p> <p>23 odds ratio of 1.28, with confidence interval</p> <p>24 of 1.12 to 1.46.</p> <p>25 Q. Where are you looking?</p>
<p style="text-align: right;">Page 291</p> <p>1 this says here.</p> <p>2 Q. Okay. If I could direct you</p> <p>3 to -- so I think you were talking about</p> <p>4 something else. We can do that first,</p> <p>5 Doctor.</p> <p>6 Dr. Hollander, when Alemany --</p> <p>7 because there's six birth cohorts here,</p> <p>8 right --</p> <p>9 A. No.</p> <p>10 Q. -- and DNBC was only one.</p> <p>11 When Alemany did an analysis of</p> <p>12 taking out the DNBC, then it was no longer</p> <p>13 statistically significant.</p> <p>14 That's what you were saying,</p> <p>15 correct?</p> <p>16 A. Well, so they're comparing,</p> <p>17 like you're saying, so they're getting</p> <p>18 similar results using the hospital diagnosis.</p> <p>19 Then they're also looking at it in boys, and</p> <p>20 they're looking at it in girls. So they're</p> <p>21 changing this thing around to see if it has</p> <p>22 any meaningful change.</p> <p>23 Q. Right. Okay.</p> <p>24 So back to my original</p> <p>25 question.</p>	<p style="text-align: right;">Page 293</p> <p>1 A. I'm looking under the prenatal</p> <p>2 acetaminophen exposure and ASC symptoms. So</p> <p>3 this is the first, second, third sentence</p> <p>4 there on the left side.</p> <p>5 Q. Right. Yeah.</p> <p>6 A. So there --</p> <p>7 Q. And we were talking about</p> <p>8 hospital diagnosis, Dr. Hollander.</p> <p>9 A. Right. And then using the</p> <p>10 hospital diagnosis, a similar effect was</p> <p>11 observed where you get an increased odds</p> <p>12 ratio, 1.14 in boys and 1.15 in girls,</p> <p>13 although, yeah, it doesn't reach statistical</p> <p>14 significance there.</p> <p>15 But it's --</p> <p>16 Q. That was my question.</p> <p>17 When using hospital diagnosis,</p> <p>18 the boys and the girls are -- both are not</p> <p>19 statistically significant, correct?</p> <p>20 A. Yeah, but except you're getting</p> <p>21 a difference in sample size, right?</p> <p>22 Q. Right. Because you're</p> <p>23 taking -- you're looking at one half and then</p> <p>24 the other, right?</p> <p>25 A. Yeah.</p>

<p>Page 294</p> <p>1 Q. Okay. And did you -- did</p> <p>2 you -- were you provided the transcript of</p> <p>3 Dr. Louie from this past Saturday?</p> <p>4 A. No.</p> <p>5 Q. Okay. So you don't know what</p> <p>6 he said at all, right?</p> <p>7 A. No.</p> <p>8 Q. Do you know who he is?</p> <p>9 A. Yes.</p> <p>10 Q. Did you talk to him before your</p> <p>11 testimony today?</p> <p>12 A. No, I didn't speak with him.</p> <p>13 Q. Okay. Do you agree that a</p> <p>14 hospital diagnosis is more accurate than a</p> <p>15 maternal report when looking at the outcome</p> <p>16 of autism spectrum disorder and ADHD?</p> <p>17 A. No. I would say that they are</p> <p>18 complementary approaches, and that if you get</p> <p>19 a positive signal using both different</p> <p>20 approaches, then that's stronger than just</p> <p>21 doing either one separately.</p> <p>22 Q. Okay. So my question for</p> <p>23 Dr. Hollander is, is hospital diagnosis more</p> <p>24 accurate and less biased than using maternal</p> <p>25 report when studying an outcome like autism</p>	<p>Page 296</p> <p>1 sample size.</p> <p>2 Q. Okay. Right. You said a lot</p> <p>3 there that I didn't ask about --</p> <p>4 A. Okay.</p> <p>5 Q. -- but let me -- let me ask you</p> <p>6 another question.</p> <p>7 We know the cohort here. We</p> <p>8 know DNBC is the cohort we're talking about.</p> <p>9 So you're talking about concordance or</p> <p>10 discordance among hospital diagnoses versus</p> <p>11 maternal report in other settings.</p> <p>12 I'm talking about this.</p> <p>13 A. Right.</p> <p>14 Q. DNBC --</p> <p>15 A. Right.</p> <p>16 Q. -- when you -- when you reduce</p> <p>17 it to hospital diagnosis, it changes the</p> <p>18 statistical significance in boys and girls,</p> <p>19 correct?</p> <p>20 A. Well, I think if you read the</p> <p>21 sentence, it says there's a similar effect,</p> <p>22 although the level of statistical</p> <p>23 significance differs.</p> <p>24 So there -- you're basically in</p> <p>25 a similar direction, but --</p>
<p>Page 295</p> <p>1 spectrum disorder and ADHD?</p> <p>2 A. I would say that there's a high</p> <p>3 concordance between the two. And so very</p> <p>4 large-scale studies that have looked at that</p> <p>5 issue have actually found like a --</p> <p>6 concordance rates of up to 98 percent.</p> <p>7 So very large genetic studies</p> <p>8 these days, like the SPARC database, their</p> <p>9 key is they want to include huge numbers of</p> <p>10 people in order to really get a handle on</p> <p>11 these genetic factors. And they don't --</p> <p>12 they no longer require like a hospital-based</p> <p>13 diagnosis, so they go on maternal report.</p> <p>14 But then they can look at the</p> <p>15 concordance rate between the maternal report</p> <p>16 and the hospital records, and it's very, very</p> <p>17 high, actually.</p> <p>18 So I think they're</p> <p>19 complementary approaches. I think that</p> <p>20 basically you get findings in similar</p> <p>21 directions. That's good. And then that's</p> <p>22 suggesting different methods getting similar</p> <p>23 findings.</p> <p>24 Yeah, a lot of the statistical</p> <p>25 significance is -- can be affected by the</p>	<p>Page 297</p> <p>1 Q. But you lose the significance,</p> <p>2 correct, Doctor?</p> <p>3 A. Yeah.</p> <p>4 Q. Okay. Now, if you look at A,</p> <p>5 Table A, right below, do you remember when we</p> <p>6 were talking before about the Masarwa</p> <p>7 meta-analysis?</p> <p>8 A. Yes.</p> <p>9 Q. And we were talking about Liew.</p> <p>10 And we were talking about the effect that it</p> <p>11 had, that bias in Liew had, on the overall</p> <p>12 statistical significance of the Masarwa</p> <p>13 medical -- meta-analysis.</p> <p>14 Do you remember that?</p> <p>15 A. I do remember that.</p> <p>16 Q. Okay. And you told me that</p> <p>17 Liew -- originally, before you agreed with</p> <p>18 me, you said that, well, Liew wasn't a high</p> <p>19 enough odds ratio and point estimate to</p> <p>20 change it, right?</p> <p>21 And I said, well, don't you</p> <p>22 have to consider the number -- the</p> <p>23 population?</p> <p>24 So I want you to look at</p> <p>25 Table A.</p>

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1 A. Uh-huh.

2 Q. And do you see that there's a

3 weight given to each study? Each cohort.

4 It's very tiny.

5 A. A random effects model, right.

6 Yeah.

7 Q. Right.

8 Do you see there's a weight

9 column?

10 A. Yes.

11 Q. How much weight does the DNBC

12 get?

13 A. It gets a lot. It gets 47

14 percent.

15 Q. It's almost half of the

16 meta-analysis, right?

17 A. Yeah.

18 Q. And why is that, Doctor?

19 A. There's a lot of people there.

20 Q. How many?

21 A. It's 61,430.

22 Q. Out of roughly 70,000, right?

23 A. Yeah. Well --

24 Q. Does it refresh your

25 recollection that the DNBC is actually what

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1 Liew studied?

2 A. Yeah, let's take a look and

3 then I --

4 Q. If you have to look at your

5 report to know that, that's fine.

6 A. No, I recall that, but I'd like

7 to take a look because truthfully there's

8 more than one Liew study, right?

9 Q. Did they study different

10 populations, Doctor?

11 A. Let's take a look.

12 Okay. So you were referring

13 back to the Masarwa article? Here.

14 Q. Well, I'm really talking

15 about --

16 A. Yeah.

17 Q. -- Table A.

18 A. Okay.

19 Q. And what's really driving this

20 is the DNBC, correct?

21 A. Well, that's by far the largest

22 sample size. So you are correct here. Their

23 weighting is high.

24 And it would go back to the

25 issue with Liew, which was 2014, right? So,

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1 I mean, you were -- yes, that is the largest

2 sample size, yeah. Okay.

3 Q. Okay. So you now get the point

4 I was trying to make before with regard to

5 Masarwa, correct?

6 MR. DOVEL: Objection. Form.

7 MR. MURDICA: He knows what I'm

8 talking about.

9 THE WITNESS: Well, I do know

10 that you were reporting that it --

11 that -- the issue is, yeah, I mean,

12 that study is the largest study, so it

13 has a big impact overall on the

14 meta-analysis because the sample size.

15 But I -- the point that I was

16 making, A, was with regards to the

17 risk ratio, it didn't pull it up

18 again.

19 And, you know, with regards to

20 that study also -- well, actually...

21 QUESTIONS BY MR. MURDICA:

22 Q. Doctor --

23 A. Yeah. Okay.

24 Q. -- because of the effect --

25 A. Yeah.

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1 Q. -- that the DNBC has on the

2 data --

3 A. Yeah.

4 Q. -- because it's such an

5 important piece, when they pull it out in

6 this analysis, which is right above the

7 table --

8 A. Yeah.

9 Q. -- the whole meta-analysis

10 loses its statistical significance, correct?

11 A. You want to direct me to the

12 figure that doesn't include that?

13 Q. Yeah, it's literally the very

14 line above that Table A, that teeny tiny

15 writing you were looking at.

16 A. Oh, the one out analysis.

17 Q. Yeah.

18 A. Okay. Well, it doesn't

19 surprise -- so it's saying the association

20 was attenuated but remained positive when --

21 so that, again, it doesn't surprise me given

22 that 47 percent of the sample size of the

23 weighting comes from that study.

24 Q. Right. If --

25 A. But -- okay.

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1 Q. If the study driving the
2 meta-analysis is pulled out, it can affect
3 the ability to reach statistical
4 significance, correct?
5 A. Yeah, except that I guess one
6 of the points that I would make here is like
7 here you have a -- in the DNBC, you know, you
8 have a more positive effect on the relative
9 risk here compared to some of the other
10 studies.
11 Q. You're talking about the 1.19?
12 What are you referring to?
13 What positive effect on the relative risk?
14 A. You know, if you look at the
15 confidence interval intervals here.
16 Q. Can you direct me to the one
17 you're talking about?
18 A. Well, look at A.
19 Q. A. Oh, ALSPAC? 1.08 --
20 A. So ALSPAC has a lower
21 confidence interval than the DNBC. The GASP
22 has a -- it's got a broader confidence
23 interval, but the point effect is lower.
24 Q. In fact, Dr. Hollander, none of
25 these studies, except the DNBC, are actually

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1 statistically significant with their point
2 effect, correct?
3 A. Well, it -- I mean, you're
4 right, in this case the DNBC is pulling up
5 the -- rather than pulling it down.
6 Q. Right.
7 So if you take it out --
8 A. Yeah.
9 Q. -- of course it's not going to
10 be statistically significant --
11 A. Right.
12 Q. -- since none of the individual
13 studies are, right?
14 Okay.
15 A. Well, you're going to have a,
16 you know, a lower overall -- so that's what
17 they're saying here, is that the association
18 was attenuated, but it still remains positive
19 even when you take it out. You still have a
20 12 percent increased risk, but that the --
21 yeah, the --
22 Q. But it's not --
23 A. -- statistical significance
24 goes away.
25 Q. Okay. All right.

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1 And, Dr. Hollander, is there
2 any reason that you can think of why
3 acetaminophen should be -- would be causal in
4 boys but not girls in terms of the outcomes
5 of ASD and ADHD?
6 A. Well, I mean, as you know, like
7 the overall risk in boys is much higher than
8 in girls, right, whether it's 4 to 1 or
9 whether it's 3 or 2 to 1. So there are
10 factors that increase the risk in boys versus
11 girls.
12 Q. From a teratology perspective,
13 if acetaminophen has anything at all to do
14 with the development of ASD or ADHD in
15 offspring, would it differentially affect
16 boys and girls?
17 A. It certainly could, yeah.
18 Q. Why?
19 A. Well, because gender could be a
20 mediating or moderating factor, right? So
21 there could be some endocrine kind of factors
22 that are moderators or potentially even
23 mediators.
24 Q. Okay. Have you considered
25 that? Do you have an expert opinion on that?

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1 A. Well, endocrine factors are
2 listed -- yeah, I do have an opinion. That's
3 one of the plausible mechanisms.
4 Q. Okay. And so --
5 A. Acetaminophen might exert its
6 effects.
7 Q. So in that theory,
8 Dr. Hollander, would there be more -- would
9 more boys or girls have autism or ADHD
10 allegedly caused by acetaminophen?
11 A. You know, I guess it depends
12 whether or not either endocrine factors or --
13 could, you know, influence -- you now have
14 all these gene by acetaminophen effects, and
15 you have all of these genetic by
16 acetaminophen effects. It could be that you
17 have gender.
18 In fact, people look at gender
19 as a covariant -- I mean, in a lot of the
20 studies where they covary for gender, they're
21 not -- you know, the results persist even
22 when you covary for sex. So in many studies,
23 the effects persist despite covarying for
24 gender.
25 Q. Dr. Hollander, are you offering

<p style="text-align: right;">Page 306</p> <p>1 an opinion here today that acetaminophen is</p> <p>2 sex-selective in terms of the outcome of ASD</p> <p>3 based on exposure during pregnancy?</p> <p>4 A. No, I'm not offering that</p> <p>5 opinion.</p> <p>6 Q. Okay. Are you offering the</p> <p>7 opinion today that APAP is sex-selective in</p> <p>8 terms of the outcome of ADHD based on</p> <p>9 exposure during pregnancy?</p> <p>10 A. I'm not offering that opinion</p> <p>11 now today. I mean, look, if you look at</p> <p>12 this, they are finding similar findings</p> <p>13 whether it's boys or girls.</p> <p>14 Obviously when you start to</p> <p>15 look at the differences then -- and they're</p> <p>16 not -- they're not seeing any statistical</p> <p>17 evidence of a difference between boys and</p> <p>18 girls, so they're not doing that. But when</p> <p>19 you're looking at it in each gender, yeah,</p> <p>20 then you're lowering the sample size, and</p> <p>21 that's affecting statistical significance.</p> <p>22 Q. Okay. Dr. Hollander, back to</p> <p>23 the sources of data.</p> <p>24 Do you think a study using a</p> <p>25 screening tool for the outcome based on</p>	<p style="text-align: right;">Page 308</p> <p>1 you want to get a big sample size. It's</p> <p>2 costly, for example. Sometimes it's a --</p> <p>3 costs more to do a study where you're getting</p> <p>4 a clinician diagnosis as opposed to either an</p> <p>5 electronic medical record or a scale kind of</p> <p>6 diagnosis. It's more costly.</p> <p>7 But I think one point that I'm</p> <p>8 making is that it doesn't have a differential</p> <p>9 effect. So if there's a -- some type of bias</p> <p>10 introduced using a scale as opposed to a gold</p> <p>11 standard diagnosis, as long as it's not a</p> <p>12 differential bias, it wouldn't bias the</p> <p>13 results towards or away from the null.</p> <p>14 Q. Did I ask about costs,</p> <p>15 Dr. Hollander?</p> <p>16 A. Well, cost is a factor in a</p> <p>17 design -- if you're going to do an epi --</p> <p>18 like I say, with cost it -- yes, I -- let me</p> <p>19 put it that way. If you have unlimited time</p> <p>20 and unlimited funds, then it's probably a</p> <p>21 good idea to get clinician diagnoses.</p> <p>22 Q. Okay. If you'd turn to the</p> <p>23 next page and look at Table 4, please.</p> <p>24 A. Uh-huh.</p> <p>25 Q. Do you see now that the authors</p>
<p style="text-align: right;">Page 307</p> <p>1 maternal report is better or worse than an</p> <p>2 outcome measure using a diagnosis?</p> <p>3 A. Well, the -- yeah. So the</p> <p>4 question would be, is there more likely to be</p> <p>5 a differential bias as a result of using a</p> <p>6 screening tool as opposed to a differential</p> <p>7 bias as opposed to using a hospital</p> <p>8 diagnosis, for example, right?</p> <p>9 Because if there's a -- if</p> <p>10 there's no differential bias, then it doesn't</p> <p>11 make any difference.</p> <p>12 Q. So the answer, Dr. Hollander,</p> <p>13 is that all things being equal, you would</p> <p>14 rather have the diagnosis, correct?</p> <p>15 A. I think it's good to be able to</p> <p>16 get similar findings with regards to outcome</p> <p>17 using different methods. So it's great if</p> <p>18 you can see similar findings both with a</p> <p>19 hospital diagnosis and with a screening tool.</p> <p>20 Q. If you could only have one or</p> <p>21 the other, Dr. Hollander, would you rather</p> <p>22 have a diagnosis or a screening tool maternal</p> <p>23 report?</p> <p>24 A. Well, so that's a challenge,</p> <p>25 you know, in epidemiology studies, is that</p>	<p style="text-align: right;">Page 309</p> <p>1 have stratified the data by sex for both</p> <p>2 autism and ADHD separately?</p> <p>3 A. Yes.</p> <p>4 Q. And they've looked at just</p> <p>5 about an even number of boys and girls for</p> <p>6 both autism and ADHD. And roughly, each --</p> <p>7 boys with autism, girls with autism, boys</p> <p>8 with ADHD, girls with ADHD, it's roughly</p> <p>9 35,000 per group, right? The number of --</p> <p>10 A. Yes, approximately.</p> <p>11 Q. Okay. And if you look at the</p> <p>12 boys for autism and ADHD, both of them are</p> <p>13 statistically significant, correct?</p> <p>14 A. Well, it looks like there's a</p> <p>15 statistically significant finding for the ASC</p> <p>16 symptoms and the ADHD symptoms.</p> <p>17 Q. Okay. And if you look at</p> <p>18 girls, there is not, correct?</p> <p>19 A. Looks like there's a positive</p> <p>20 association but that it doesn't reach --</p> <p>21 well, actually -- but that -- yeah, it looks</p> <p>22 like it doesn't reach statistical</p> <p>23 significance there.</p> <p>24 Q. Right.</p> <p>25 And one of the factors that you</p>

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1 think about when you do Bradford Hill is an
 2 overall concordance, a does this make sense
 3 factor, right?
 4 A. Do you mean coherence --
 5 Q. Yes --
 6 A. -- or do you mean --
 7 Q. -- coherence.
 8 A. Okay.
 9 Q. This would not pass the
 10 coherence test, correct, Doctor?
 11 Because it doesn't make sense,
 12 as you just testified, for there to be a
 13 difference between boys and girls.
 14 A. I don't think that I testified
 15 that it doesn't make sense for there to be a
 16 difference between boys and girls.
 17 Q. Okay. What is your expert
 18 opinion about why there's a difference
 19 between boys and girls if it's -- that is
 20 coherent with the data?
 21 A. Well, one, again, is that --
 22 you know, the obvious reason is that
 23 you're -- if you're cutting the sample size
 24 in half, then, you know, your power goes
 25 down. So that's probably the biggest reason.

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1 Q. You have no mechanism otherwise
 2 to explain why there's a difference. You're
 3 saying this is just a statistical anomaly,
 4 correct?
 5 A. Well, no. So that's one
 6 option, is that you're dealing with a smaller
 7 sample size.
 8 I guess I tried to offer an
 9 opinion with regards to whether or not there
 10 could be, you know, other factors that could
 11 mediate or moderate the effect.
 12 Q. Right.
 13 And I asked you if you had an
 14 expert opinion sitting here today --
 15 A. Yeah.
 16 Q. -- on what those factors were
 17 and the mechanism by which they occur, and
 18 you said you do not, correct?
 19 A. Well, no. All I said, that
 20 it fits in with this idea of certain hormonal
 21 factors, but I wasn't offering a specific
 22 opinion.
 23 Q. Okay. Did you look at the
 24 supplemental materials related to this study?
 25 A. I don't recall.

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1 Q. Is it on your reliance list?
 2 A. Let's take a look.
 3 I think that it's hard to
 4 determine because I don't see the specific
 5 page numbers. So it may not be determinable.
 6 (Hollander Exhibit 58 marked
 7 for identification.)
 8 QUESTIONS BY MR. MURDICA:
 9 Q. I'm going to mark the
 10 supplemental materials as Exhibit 58.
 11 Dr. Hollander, you should now
 12 have in front of you what's been marked as
 13 Exhibit 58.
 14 Based on your review -- do you
 15 have Exhibit 58 in front of you?
 16 A. Yes, I do.
 17 Q. Based on your review of the
 18 first page of Exhibit 58, does this appear to
 19 be supplementary material to the Alemany
 20 article which is Exhibit 57?
 21 A. Well, it does say supplementary
 22 material, and it does relate to the title of
 23 the article, and it does include the similar
 24 authors, so it does appear that this is the
 25 supplementary material to the article.

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1 Q. Okay. And if you would turn to
 2 the fifth page, which says, "Methods S2," and
 3 it's a description of the acetaminophen
 4 prenatal exposure assessment.
 5 A. Yeah.
 6 Q. Okay. Now, we were just
 7 talking, and you saw in the Alemany article
 8 there's six birth cohorts, right? And these
 9 are the -- and these are a more descriptive
 10 version of the six that you saw the acronyms
 11 for in the Alemany article.
 12 Fair?
 13 A. Yes. This is a description of
 14 each of the different cohorts.
 15 Q. Okay. And one of the features
 16 of all the cohorts is that no one asked, and
 17 the mothers did not report, the exact day in
 18 pregnancy that acetaminophen was used or for
 19 exactly how long for each use, correct?
 20 A. Well, if you look at the
 21 methods here -- so, for example, in the
 22 ALSPAC cohort, the mothers get a
 23 questionnaire at 18 and 32 weeks.
 24 Q. Right.
 25 The mothers are getting

<p style="text-align: right;">Page 314</p> <p>1 questionnaires, and they're not saying, I 2 used acetaminophen on days 3 through 17 and 3 days 90 through 94 of my pregnancy, correct? 4 A. Well, it differs a little bit 5 per cohort, right? 6 Q. Sure. 7 A. So the first one, you know, 8 again has this questionnaire at 18 and 32. 9 The DNBC cohort gets a 10 telephone interview at the 12th and the 30th 11 week and postpartum. 12 And then there are -- there is 13 a list of different medicines. So then... 14 Q. Doctor, I'd like to you -- 15 A. Each cohort has a -- slightly 16 different methods in terms of exposure. 17 Q. The way that Alemany counted 18 them, Doctor -- and feel free to take a look 19 at the six descriptions because it's only a 20 page and a half -- is that if acetaminophen 21 was ever used during the pregnancy at any 22 time, it was -- they were counted as users 23 for the purpose of the meta-analysis, 24 correct? 25 And you can take a minute to</p>	<p style="text-align: right;">Page 316</p> <p>1 exposures starting one month before becoming 2 pregnant, correct? 3 A. No. 4 Q. Okay. 5 A. So it says here mothers were 6 asked if they had taken medications from the 7 month before becoming pregnant, in the GASPII 8 and the INMA, or beginning of pregnancy, in 9 the RHEA. So there's a difference depending 10 on the study. 11 Q. My question was, with the 12 exception of one, these cohorts counted 13 exposures starting one month before becoming 14 pregnant, correct? 15 Are you looking on page -- 16 A. I'm looking at exposure in the 17 methods section of the manuscript. 18 Q. Ah. Okay. Well -- 19 A. Because in that, it doesn't say 20 that. 21 Q. And that's why, when 22 epidemiologists are looking at literature, 23 they look at the supplemental tables, so they 24 can figure out the full methods in the data, 25 right?</p>
<p style="text-align: right;">Page 315</p> <p>1 verify that before you answer. 2 A. Well, it does say that -- oh, I 3 see. One moment. 4 Yeah. Well, these were 5 classified as ever-exposed if they reported 6 having taken any dose of acetaminophen in the 7 defined prenatal exposure period. Otherwise 8 they were classified as nonexposed. So, 9 yeah. 10 Q. Right. 11 You agree with me that for the 12 purposes of this meta-analysis, Alemany 13 counted them as exposed if they ever took one 14 single pill of acetaminophen at some point 15 during the exposure period, correct? 16 A. Well, that's what it says in 17 the methods section, yes. 18 Q. Okay. You don't have any 19 reason to doubt that that's what Alemany did 20 when they wrote this in their supplemental 21 materials, right? 22 A. No. 23 Q. Okay. Now, if you look at -- 24 and I think you just did -- the -- with the 25 exception of one, these cohorts all counted</p>	<p style="text-align: right;">Page 317</p> <p>1 A. Well, it's possible that some 2 information may be included in the 3 supplemental material that's not included in 4 the main manuscript. 5 Q. All right. Well, why don't we 6 look at the supplemental material and I'll 7 ask my question again. 8 With the exception of one, 9 these cohorts counted exposures starting one 10 month before becoming pregnant, correct? 11 A. All right. Let's review that 12 again because that's not what it says in the 13 methods. 14 Well, no -- 15 Q. Okay. 16 A. -- I mean, that's not what it 17 says at DNBC. Mothers are classified as 18 users of acetaminophen during pregnancy if 19 they've taken any dose of acetaminophen at 20 any time up during pregnancy. 21 So it doesn't say anything 22 about taking it prior to -- one month prior. 23 So that's not true with regard to the DNBC. 24 Q. Okay. Are you sure, Doctor? 25 A. I'm reading it here from the --</p>

<p>Page 318</p> <p>1 Q. Supplemental materials?</p> <p>2 A. Yeah. Mothers were classified</p> <p>3 as users of acetaminophen during pregnancy if</p> <p>4 they had taken any dose of acetaminophen at</p> <p>5 any time up during pregnancy.</p> <p>6 And if you look at the methods</p> <p>7 also, it doesn't say that with regards to the</p> <p>8 DNBC cohort. So that's not -- that's not a</p> <p>9 correct statement with regard to that cohort.</p> <p>10 Q. Okay, Doctor.</p> <p>11 A. This also --</p> <p>12 Q. Look up three -- look three</p> <p>13 sentences up. Then look at the rest of them.</p> <p>14 Did you consider any of this</p> <p>15 before you rendered your opinions,</p> <p>16 Dr. Hollander?</p> <p>17 MR. DOVEL: Just one second.</p> <p>18 He was in the middle of answering</p> <p>19 another question.</p> <p>20 Are you going to withdraw the</p> <p>21 earlier question?</p> <p>22 The record is very muddy. I</p> <p>23 don't know what question is being</p> <p>24 answered.</p> <p>25 I'll state for the record that</p>	<p>Page 320</p> <p>1 I'm sorry. So there's a statement here, but</p> <p>2 then it seems to contradict at the end.</p> <p>3 So --</p> <p>4 Q. Dr. Hollander, didn't you --</p> <p>5 A. -- I'm seeing a lot of</p> <p>6 inconsistencies here.</p> <p>7 Q. The DNBC is the basis of all</p> <p>8 the data that you're opining your causation</p> <p>9 opinion on, right?</p> <p>10 A. No.</p> <p>11 MR. DOVEL: Objection. Form.</p> <p>12 QUESTIONS BY MR. MURDICA:</p> <p>13 Q. Do you not know the details</p> <p>14 around the DNBC and how it was studied?</p> <p>15 A. I see that there's</p> <p>16 contradictory information here, both in terms</p> <p>17 of methods of the article as well as</p> <p>18 contradictory statements even within the</p> <p>19 summary here.</p> <p>20 Q. Right.</p> <p>21 But didn't --</p> <p>22 A. Supplementary material.</p> <p>23 Q. But you realize that you're</p> <p>24 putting these opinions out to the Southern</p> <p>25 District of New York, a federal court --</p>
<p>Page 319</p> <p>1 the witness --</p> <p>2 MR. MURDICA: Well, what you</p> <p>3 understand or not doesn't really</p> <p>4 matter.</p> <p>5 MR. DOVEL: Excuse me. Excuse</p> <p>6 me.</p> <p>7 He was in the middle of</p> <p>8 answering a question --</p> <p>9 MR. MURDICA: This is my --</p> <p>10 you're interrupting my question. You</p> <p>11 just be quiet over there.</p> <p>12 MR. DOVEL: He was in the</p> <p>13 middle of answering the question, and</p> <p>14 then you posed another one before he'd</p> <p>15 finished. And the record would be</p> <p>16 fraudulent to suggest otherwise.</p> <p>17 MR. MURDICA: You're funny.</p> <p>18 QUESTIONS BY MR. MURDICA:</p> <p>19 Q. Dr. Hollander --</p> <p>20 MR. DOVEL: I try to amuse.</p> <p>21 MR. MURDICA: Good job.</p> <p>22 QUESTIONS BY MR. MURDICA:</p> <p>23 Q. Dr. Hollander --</p> <p>24 A. Well, I would say, look, in</p> <p>25 here there's two inconsistent statements.</p>	<p>Page 321</p> <p>1 A. Uh-huh.</p> <p>2 Q. -- and you didn't even bother</p> <p>3 to go understand the DNBC?</p> <p>4 MR. DOVEL: Objection. Form.</p> <p>5 THE WITNESS: Yeah, I think</p> <p>6 that's an incorrect statement on many</p> <p>7 different levels.</p> <p>8 QUESTIONS BY MR. MURDICA:</p> <p>9 Q. Okay.</p> <p>10 A. But, yes, A, this is an</p> <p>11 important study. B, I considered the study</p> <p>12 in my opinions.</p> <p>13 It's not the only study that I</p> <p>14 included within my opinions, so it's --</p> <p>15 Q. The DNBC cohort is a</p> <p>16 foundational --</p> <p>17 A. It's a --</p> <p>18 Q. -- cohort for everything you're</p> <p>19 opining on.</p> <p>20 A. It's an important cohort, yes.</p> <p>21 Q. Okay. So you know now that the</p> <p>22 DNBC and all of the others here, except for</p> <p>23 RHEA, counted exposure starting four weeks</p> <p>24 before pregnancy or four weeks before</p> <p>25 conception, correct?</p>

<p style="text-align: right;">Page 322</p> <p>1 MR. DOVEL: Objection. Form.</p> <p>2 THE WITNESS: I don't see that,</p> <p>3 actually.</p> <p>4 QUESTIONS BY MR. MURDICA:</p> <p>5 Q. Okay.</p> <p>6 A. And I'm not seeing -- I don't</p> <p>7 see that in the GASPII cohort either.</p> <p>8 Q. Okay.</p> <p>9 A. So I think that's -- it</p> <p>10 doesn't -- that's not right.</p> <p>11 Q. Okay.</p> <p>12 A. So I disagree.</p> <p>13 Q. All right. Well, let's read</p> <p>14 the second sentence. I'll let you read it.</p> <p>15 "Mothers were classified" -- go</p> <p>16 ahead, you can read it out loud.</p> <p>17 A. Okay. "Mothers were classified</p> <p>18 as users of acetaminophen during pregnancy if</p> <p>19 they had taken any dose of acetaminophen at</p> <p>20 any time up to week 32 of pregnancy or the</p> <p>21 month before becoming pregnant."</p> <p>22 All right. You're right. It</p> <p>23 does say it in that sentence.</p> <p>24 Q. Okay.</p> <p>25 A. Let's take a look.</p>	<p style="text-align: right;">Page 324</p> <p>1 Alemany, if a mother took one pill of</p> <p>2 acetaminophen 29 days before becoming</p> <p>3 pregnant, the child was counted as exposed to</p> <p>4 acetaminophen, correct?</p> <p>5 A. Well, not for all of the</p> <p>6 cohorts, but I guess that's a possibility for</p> <p>7 some of these.</p> <p>8 Q. For ALSPAC, DNBC --</p> <p>9 A. Right.</p> <p>10 Q. -- GASPII, Generation R and</p> <p>11 INMA cohort, that was counted as an exposed</p> <p>12 pregnancy, correct?</p> <p>13 A. It's possible that somebody</p> <p>14 could be classified and fall into that</p> <p>15 category.</p> <p>16 Q. Right.</p> <p>17 And did you factor that into</p> <p>18 your analysis, Dr. Hollander?</p> <p>19 A. Well, I would factor it into my</p> <p>20 analysis because --</p> <p>21 Q. Would or wouldn't? I'm sorry.</p> <p>22 A. I would.</p> <p>23 Q. Okay.</p> <p>24 A. Because the dose-response</p> <p>25 relationship is clear from a number of</p>
<p style="text-align: right;">Page 323</p> <p>1 Q. Just let me know when you're</p> <p>2 satisfied that I'm right about what I tried</p> <p>3 to start asking you about 15 minutes ago.</p> <p>4 A. Okay. Let's take a look.</p> <p>5 MR. MURDICA: Let the record</p> <p>6 reflect that the doctor is looking at</p> <p>7 Exhibit 57 and not Exhibit 58 right</p> <p>8 now.</p> <p>9 THE WITNESS: Well, I'm</p> <p>10 reviewing the manuscript that you're</p> <p>11 referring to to be able to put it into</p> <p>12 context, what you're putting in front</p> <p>13 of me in terms of the supplementary</p> <p>14 material.</p> <p>15 Okay.</p> <p>16 QUESTIONS BY MR. MURDICA:</p> <p>17 Q. Okay. So do you now agree with</p> <p>18 me that with the exception of the RHEA</p> <p>19 cohort, all the cohorts counted exposure, if</p> <p>20 there was exposure, one month before becoming</p> <p>21 pregnant or conceiving?</p> <p>22 A. Well, again, between one month</p> <p>23 prior to and the end of pregnancy.</p> <p>24 Q. Right.</p> <p>25 So in -- for the purposes of</p>	<p style="text-align: right;">Page 325</p> <p>1 studies, including those studies that used</p> <p>2 biomarkers.</p> <p>3 So, first, with biomarkers,</p> <p>4 when you're able to assess dosage during the</p> <p>5 second or third trimester or in studies that</p> <p>6 look at duration, you have a clearcut</p> <p>7 exposure response.</p> <p>8 So although I guess it's</p> <p>9 theoretically possible that somebody would be</p> <p>10 classified, it doesn't -- it's not -- it's</p> <p>11 not consistent with the idea of a</p> <p>12 dose-response finding, and it's not</p> <p>13 consistent with a finding of dosing over</p> <p>14 time.</p> <p>15 Q. And, Dr. Hollander, we're only</p> <p>16 getting to these one at a time --</p> <p>17 A. Yeah.</p> <p>18 Q. -- and it seems that as each</p> <p>19 one, you realize that there's problems you</p> <p>20 didn't appreciate, you start pointing to the</p> <p>21 others. And we're going to get to them.</p> <p>22 But did you consider in Alemany</p> <p>23 that an exposure counted even if there was</p> <p>24 one pill of acetaminophen and even if it</p> <p>25 wasn't during pregnancy?</p>

<p style="text-align: right;">Page 326</p> <p>1 MR. DOVEL: Objection. Form.</p> <p>2 THE WITNESS: I guess that gets</p> <p>3 to the issue of whether or not there</p> <p>4 could be a misclassification of</p> <p>5 exposure.</p> <p>6 QUESTIONS BY MR. MURDICA:</p> <p>7 Q. Okay. And, Doctor --</p> <p>8 A. And I guess there are different</p> <p>9 ways to assess misclassification of exposure.</p> <p>10 Q. Right.</p> <p>11 And --</p> <p>12 A. And I think -- so maybe this</p> <p>13 Alemany study may not address that potential</p> <p>14 the same way that some of the other studies</p> <p>15 do.</p> <p>16 Q. Okay. Dr. Hollander, do you</p> <p>17 know how the symptoms were assessed in</p> <p>18 Alemany and whether they followed the DSM?</p> <p>19 A. Well, it looks like it's a</p> <p>20 little bit different because they're using</p> <p>21 terminology such as autism spectrum</p> <p>22 conditions. So -- and the issue has to do</p> <p>23 with whether there's misclassification of</p> <p>24 exposure and/or whether there's</p> <p>25 misclassification in terms of outcome.</p>	<p style="text-align: right;">Page 328</p> <p>1 depression, maternal mental health, as, I</p> <p>2 think you said, a factor associated with the</p> <p>3 outcomes of autism and the outcomes of ADHD,</p> <p>4 correct?</p> <p>5 A. Well, the issue was -- gets to</p> <p>6 whether or not there's some kind of a genetic</p> <p>7 confounding.</p> <p>8 However, it only has an effect</p> <p>9 on the relationship between the exposure and</p> <p>10 the outcome if that results in a behavior</p> <p>11 that directly influences the exposure.</p> <p>12 Q. Dr. Hollander, had you looked</p> <p>13 at this data and the doubling here in the --</p> <p>14 in the population that ended up with autism</p> <p>15 in terms of maternal mental health?</p> <p>16 A. Yes, I'm familiar with that.</p> <p>17 Q. Okay. And did you know that</p> <p>18 that was the case, that there was a doubling</p> <p>19 in the DNBC?</p> <p>20 A. It -- it's essentially the same</p> <p>21 issue that you had alluded to before with the</p> <p>22 Masarwa 2020 paper as well --</p> <p>23 Q. Okay.</p> <p>24 A. -- which is the issue of</p> <p>25 genetic confounding, right?</p>
<p style="text-align: right;">Page 327</p> <p>1 Q. Okay. Dr. Hollander, if you</p> <p>2 would turn to Table S2 in Exhibit 58, please.</p> <p>3 A. Let's see. What page is that</p> <p>4 on?</p> <p>5 Q. 17. Sorry, I should have given</p> <p>6 you a page number.</p> <p>7 You ready?</p> <p>8 A. Yes.</p> <p>9 Q. Okay. If you look -- and I'm</p> <p>10 going to ask you questions about the DNBC.</p> <p>11 Do you recall earlier we talked</p> <p>12 about that they did a -- they did parental</p> <p>13 questionnaire and then they also looked at</p> <p>14 medical diagnosis, right?</p> <p>15 A. Correct.</p> <p>16 Q. Okay. And if you look on the</p> <p>17 far right for both groups, the children that</p> <p>18 end up with autism had mothers who had mental</p> <p>19 health issues during pregnancy at double the</p> <p>20 rate of the children that were normal,</p> <p>21 correct?</p> <p>22 A. I see that.</p> <p>23 Q. Right.</p> <p>24 And that -- based on the</p> <p>25 questions I asked you earlier, you recognize</p>	<p style="text-align: right;">Page 329</p> <p>1 Q. Right. And --</p> <p>2 A. And it's the same issue again</p> <p>3 as -- so if that genetic confounding or that</p> <p>4 maternal behavior directly affects the</p> <p>5 exposure, then it's relevant. Otherwise,</p> <p>6 it's not. Because the -- if you look at the</p> <p>7 maternal mental health behavior, it certainly</p> <p>8 could be a mediator or a moderator of the</p> <p>9 effect of the exposure and the outcome.</p> <p>10 Q. Okay.</p> <p>11 A. So if you take it away, then</p> <p>12 you take away the effect.</p> <p>13 So, you know, we know that</p> <p>14 these things are gene-by-environment</p> <p>15 interactions. This is only an issue if it</p> <p>16 directly affects the behavior at question,</p> <p>17 which is the taking of the medicine. And you</p> <p>18 can -- you wouldn't want to take away the</p> <p>19 familial or the genetic factors if they</p> <p>20 directly affect, again, the mediators and</p> <p>21 moderators.</p> <p>22 So the genetic effects affect</p> <p>23 how the APAP produces the outcome, or it</p> <p>24 moderates the levels of APAP, then you</p> <p>25 wouldn't want to be able to take that away.</p>

<p style="text-align: right;">Page 330</p> <p>1 In fact, you would need that 2 gene-by-environment interaction in order to 3 get the outcome. 4 Q. If patients -- if mothers with 5 mental health issues -- 6 A. Right. 7 Q. -- take acetaminophen more than 8 mothers without mental health issues, it 9 could be mental health, in fact, that's the 10 mediator that attenuates the acetaminophen 11 association you're seeing, correct? 12 A. Well, it could be that the 13 mental health issues are associated with -- 14 and again, I get back to my example of the 15 cannabinoid-1 receptor or the FAAH. So let's 16 say that women with mental health problems 17 have genetic polymorphisms for the CB1 18 receptor. They have genetic polymorphisms 19 for FAAH. 20 If APAP exerts its effects 21 through the endocannabinoid system but there 22 are familial, genetic factors, then it's not 23 a confounder. It's actually a mediator of 24 the effect for the compound. So it's that 25 gene by environment -- you need that in order</p>	<p style="text-align: right;">Page 332</p> <p>1 But the effect was actually 2 really small, and so those individuals 3 interpreted it by saying, look, there's a 4 relationship. It's very small. It wouldn't 5 work as a confounder to wipe out the 6 association, so you can't blame it on the 7 APAP-taking aspect of the mother. 8 Again, that sort of gets back 9 to the blame-the-mother approach as well, 10 that somehow, you know, these women with 11 mental health problems are more likely to be 12 taking APAP. But it's not an issue if the 13 genetic and familial factors associated with 14 the mental health problems mediate the 15 expression or the effect of APAP on the 16 outcome. 17 Q. Dr. Hollander, you're blaming 18 the mother as well if you are blaming APAP 19 because the mother took the APAP, right? 20 Have you considered that when 21 you talk to your patients about causation? 22 I'll ask another question. 23 A. Well -- 24 MR. DOVEL: Just a second. He 25 wants to answer.</p>
<p style="text-align: right;">Page 331</p> <p>1 to get the effect. 2 Q. And, Doctor -- 3 A. And it would still be an effect 4 of the exposure. It would be an effect of 5 the exposure being mediated through that 6 genetic variation. 7 Q. And, Dr. Hollander, if you're 8 being fair, it could also be vice versa, 9 could it not? 10 A. How would that be the case? 11 Q. The way I just explained it. 12 A. Let me see if I can try to 13 understand that. So -- 14 Q. Have you seen data that women 15 with depression are more likely users of 16 acetaminophen? 17 A. I have seen publications that 18 talk about behavioral factors as it relates 19 to acetaminophen use. 20 Q. And -- 21 A. So like the Lupattelli study. 22 So they suggested that, you know, neuroticism 23 or openness, which are two traits in the 24 mothers, you know, could potentially have an 25 effect on APAP usage.</p>	<p style="text-align: right;">Page 333</p> <p>1 THE WITNESS: Well -- 2 MR. MURDICA: Hey, listen, you 3 don't tell me when he wants to answer. 4 He wasn't answering. You don't help. 5 MR. DOVEL: No, he was 6 answering. He was answering. 7 MR. MURDICA: Go ahead, 8 Dr. Hollander. 9 MR. DOVEL: The record will 10 show he was answering. 11 MR. MURDICA: He wasn't. 12 THE WITNESS: Actually, you 13 know what I am blaming is I'm -- 14 QUESTIONS BY MR. MURDICA: 15 Q. The lack of a microphone? 16 A. I'm blaming the risk versus 17 benefit discussion as it relates to the APAP. 18 So that's what I'm blaming. 19 Q. Dr. Hollander, are you aware 20 that maternal depression is highly related to 21 increased APAP use? 22 A. I'm aware that there can be 23 some familial or maternal factors that 24 influence APAP use but that those factors are 25 relatively small. And you'd have to have a</p>

<p style="text-align: right;">Page 334</p> <p>1 really big impact in order to wipe out the</p> <p>2 association between the exposure and the</p> <p>3 outcome, and that just doesn't happen.</p> <p>4 Q. And that's based on what,</p> <p>5 Doctor?</p> <p>6 A. Well, that's based on the</p> <p>7 Lupattelli study where she addressed that</p> <p>8 specific question.</p> <p>9 Q. Okay.</p> <p>10 A. She talked about maternal</p> <p>11 traits and whether those maternal traits</p> <p>12 influenced the APAP-taking behavior. And</p> <p>13 then she related it to different kinds of</p> <p>14 exposures like SSRIs.</p> <p>15 In her analysis of that, she</p> <p>16 felt that the -- that could be -- play more</p> <p>17 of a role with certain kinds of exposures and</p> <p>18 less of a role with other exposures.</p> <p>19 Q. Are you familiar --</p> <p>20 A. So she determined that that</p> <p>21 could be a potential confounder as it relates</p> <p>22 to determining relationship between SSRIs and</p> <p>23 neurodevelopmental outcomes, but that it</p> <p>24 wasn't a -- it wasn't a role with regards to</p> <p>25 APAP use and neurodevelopmental outcomes.</p>	<p style="text-align: right;">Page 336</p> <p>1 A. Yes, I am.</p> <p>2 Q. Okay. Welcome back.</p> <p>3 Dr. Hollander, one of your --</p> <p>4 one of the aspects of your opinion is that</p> <p>5 because ADHD and autism, in your view, share</p> <p>6 a symptom, that being hyperactivity, that</p> <p>7 anything that causes hyperactivity is a cause</p> <p>8 of both autism and ADHD, correct?</p> <p>9 A. No.</p> <p>10 Q. Okay. Could you please turn to</p> <p>11 page 32 of your report?</p> <p>12 A. This is the original report or</p> <p>13 the rebuttal report?</p> <p>14 Q. Sorry, the rebuttal report.</p> <p>15 A. Yeah. Okay.</p> <p>16 Q. Okay. On page 32, on the</p> <p>17 bottom paragraph, it says, "Here,</p> <p>18 hyperactivity is a symptom domain that is a</p> <p>19 core feature of ADHD and an associated domain</p> <p>20 of ASD. If acetaminophen exposure during</p> <p>21 pregnancy causes hyperactivity in ASD and</p> <p>22 ADHD individuals, and if hyperactivity is a</p> <p>23 common feature of ADHD and ASD, then</p> <p>24 acetaminophen causes ADHD and ASD."</p> <p>25 Did I read that correctly?</p>
<p style="text-align: right;">Page 335</p> <p>1 MR. DOVEL: Time for a break</p> <p>2 when you get a chance.</p> <p>3 QUESTIONS BY MR. MURDICA:</p> <p>4 Q. Okay. Have you seen the</p> <p>5 Bandoli study, Doctor?</p> <p>6 A. It doesn't come to my mind</p> <p>7 immediately --</p> <p>8 Q. Okay.</p> <p>9 A. -- but I'd be glad to look at</p> <p>10 that.</p> <p>11 MR. MURDICA: Sure, we'll take</p> <p>12 a break.</p> <p>13 VIDEOGRAPHER: The time right</p> <p>14 now is 5 p.m. We are off the record.</p> <p>15 (Off the record at 5:00 p.m.)</p> <p>16 VIDEOGRAPHER: The time right</p> <p>17 now is 5:15 p.m. We're back on the</p> <p>18 record.</p> <p>19 QUESTIONS BY MR. MURDICA:</p> <p>20 Q. Welcome back, Dr. Hollander.</p> <p>21 Are you ready to proceed?</p> <p>22 A. Yes, I am. Thanks.</p> <p>23 Q. Okay. All right.</p> <p>24 Dr. Hollander, are you ready to</p> <p>25 proceed?</p>	<p style="text-align: right;">Page 337</p> <p>1 A. Yes.</p> <p>2 Q. Okay. Do you want to make any</p> <p>3 corrections to the words in those sentences,</p> <p>4 or do you stand by those words?</p> <p>5 A. Well, I -- maybe I can talk a</p> <p>6 little about -- so the basic idea is we're</p> <p>7 looking at symptom domains that present</p> <p>8 across both neurodevelopmental disorders. I</p> <p>9 was using hyperactivity as an example of a</p> <p>10 symptom domain that cuts across both</p> <p>11 disorders. I wasn't suggesting in any way</p> <p>12 that it -- that was the key symptom domain</p> <p>13 that relates the two together.</p> <p>14 And in fact, really what I see</p> <p>15 is that, you know, my work has been in</p> <p>16 compulsivity and impulsivity, and both</p> <p>17 conditions share features of compulsivity and</p> <p>18 impulsivity.</p> <p>19 So if I could say it, the</p> <p>20 compulsivity, both of the disorders have</p> <p>21 impairment in set shifting, the ability to,</p> <p>22 you know, let go of stimuli and then refocus</p> <p>23 on other issues. That set shifting deficit</p> <p>24 or executive function deficit is like a key</p> <p>25 feature in terms of the, you know,</p>

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1 attentional issues in ADHD.
 2 And clearly individuals with
 3 ASD also have difficulties in term of set
 4 shifting.
 5 The impulsivity, which tightly
 6 overlaps with the hyperactivity, is also a
 7 feature -- the impulsivity -- the
 8 impulsivity/hyperactivity is one domain, and
 9 then the impulsivity is a major component as
 10 an associated symptom in ASD.
 11 And I would -- and I would
 12 relate the compulsivity and impulsivity that
 13 I'm describing to the frontostriatal
 14 circuitry and the frontolimbic circuitry
 15 that's impacted in both disorders.
 16 Q. Do you remember my question?
 17 A. Well, I think your question had
 18 to do with whether or not hyperactivity was a
 19 symptom domain or feature of both disorders.
 20 Q. No.
 21 My question --
 22 A. Yeah.
 23 Q. -- Doctor, is, do you -- the
 24 two sentences that we read together that
 25 begins with "here" and ends with the word

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1 "ASD" on page 32, do you want to correct the
 2 words in those two sentences or leave them
 3 as-is?
 4 A. Well --
 5 Q. I'm giving you a chance.
 6 A. Right.
 7 And what I'm -- so what I'm
 8 suggesting is I might modify hyperactivity to
 9 include hyperactivity/impulsivity.
 10 Q. You --
 11 A. As a --
 12 Q. -- don't mean -- Dr. Hollander
 13 is not here to tell the Court and the world
 14 that anything that has a -- anything that
 15 causes hyperactivity causes autism and ADHD,
 16 correct? That is not your testimony?
 17 A. Could you repeat that question
 18 again?
 19 Q. Sure.
 20 Are you here to tell the world
 21 that something associated with hyperactivity
 22 means it causes autism and ADHD?
 23 A. No.
 24 Q. Okay. You're not -- you're not
 25 saying that if acetaminophen is associated

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1 with hyperactivity, then it must also cause
 2 ASD and ADHD, correct?
 3 A. No, I'm not saying that.
 4 Q. Okay. And impulsivity is not a
 5 feature of ADHD, right?
 6 A. Well, it is. The
 7 hyperactivity/impulsivity domain, yeah.
 8 Q. Is it a feature of all ADHD?
 9 A. It's a feature of those who
 10 have the combined type or the hyperactive
 11 type.
 12 Q. Okay. So not every --
 13 A. Not the inattentive type.
 14 Q. Okay. And is hyperactivity a
 15 feature of everyone diagnosed with ADHD?
 16 A. No. It's a symptom of those
 17 who have the hyperactivity/impulsivity
 18 subtype, not just those who just have the
 19 inattention subtype.
 20 Q. Okay. If you turn to page 22
 21 of your rebuttal report, please, Doctor.
 22 I want to focus you on the last
 23 sentence. Let me know when you're there.
 24 I'll read it, and you tell me if I read it
 25 correctly.

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1 Do you see the last sentence
 2 that begins "to the contrary"? Page 22 of
 3 your rebuttal.
 4 A. Could you read the sentence
 5 above that? Because somehow it's not --
 6 Q. Yeah.
 7 It's the paragraph that starts,
 8 "In addition" -- that doesn't look right
 9 because you have a sub-footnote there.
 10 A. Oh, I see. I gotcha here.
 11 Q. Well -- oh, you have a
 12 different version than I do.
 13 A. I don't think so.
 14 Q. I'm looking here. You're on
 15 23. Huh. Go -- oh --
 16 A. "In addition."
 17 Q. Huh. I have to admit, I'm
 18 puzzled.
 19 A. Or this "in addition" back
 20 here? Baccarelli --
 21 Q. Oh, specificity is -- ah, right
 22 here. "To the contrary."
 23 A. Okay. Gotcha. Sorry.
 24 Q. Okay. It does seem -- the
 25 pages are not matched up. All right. We'll

<p style="text-align: right;">Page 342</p> <p>1 mark that and try to figure it out later.</p> <p>2 We'll take a copy of it.</p> <p>3 Dr. Hollander, you state, "To</p> <p>4 the contrary, as I have discussed in great</p> <p>5 detail in my initial report, it is widely</p> <p>6 accepted that neurodevelopmental disorders,</p> <p>7 including ASD and ADHD, share important</p> <p>8 neurogenetic physiological, structural and</p> <p>9 psychological traits, Barch 2020, period."</p> <p>10 Did I read that correctly?</p> <p>11 A. Yes.</p> <p>12 Q. Okay. Now, is Barch a</p> <p>13 publication that you're familiar with?</p> <p>14 A. Yeah, it's a publication that</p> <p>15 I've considered in my materials considered</p> <p>16 list.</p> <p>17 Q. Okay. And Barch stands for the</p> <p>18 proposition that ASD and ADHD share important</p> <p>19 neurogenetic, et cetera, traits, right?</p> <p>20 A. Correct.</p> <p>21 (Hollander Exhibits 59 and 60</p> <p>22 marked for identification.)</p> <p>23 QUESTIONS BY MR. MURDICA:</p> <p>24 Q. Okay. Mark Barch -- we're</p> <p>25 going to mark that report that's different as</p>	<p style="text-align: right;">Page 344</p> <p>1 talk about bipolar disorder and major</p> <p>2 depression. So they use different examples.</p> <p>3 But the concept is -- can be</p> <p>4 certainly -- the concept can be applied and</p> <p>5 is appropriate to the transdiagnostic symptom</p> <p>6 domains that cut across ASD and ADHD and map</p> <p>7 onto their underlying brain circuitry and</p> <p>8 neurogenetic factors.</p> <p>9 Q. Dr. Hollander, it doesn't say</p> <p>10 that. You were citing Barch 2020 as</p> <p>11 background, not specific to ASD and ADHD,</p> <p>12 correct?</p> <p>13 A. It's talking about a</p> <p>14 transdiagnostic approach to neuropsychiatric</p> <p>15 disorders.</p> <p>16 Q. Okay. And you can have --</p> <p>17 A. Yeah.</p> <p>18 Q. Dr. Hollander, you can have</p> <p>19 symptoms but not have a disorder, correct?</p> <p>20 A. Well, yes. I mean, you can</p> <p>21 have symptoms and symptom domains and not</p> <p>22 have a disorder.</p> <p>23 Q. Right.</p> <p>24 You would only be given a</p> <p>25 disorder in the diagnostic manual if the</p>
<p style="text-align: right;">Page 343</p> <p>1 59, and we'll mark Barch as 60.</p> <p>2 Okay. Dr. Hollander, you now</p> <p>3 have in front of you a document that's been</p> <p>4 marked as Exhibit 60 by author Deanna Barch.</p> <p>5 Do you see that?</p> <p>6 A. Yes.</p> <p>7 Q. Is this what you were</p> <p>8 referencing in your rebuttal report with the</p> <p>9 Barch citation?</p> <p>10 A. I believe so, yes.</p> <p>11 Q. Okay. Dr. Hollander, can you</p> <p>12 point us to where this article says anything</p> <p>13 about attention-deficit/hyperactivity</p> <p>14 disorder or autism spectrum disorder?</p> <p>15 A. Well, I mean, this is taking</p> <p>16 the approach -- again, we're highlighting</p> <p>17 that symptom domains can be transdiagnostic</p> <p>18 and can map onto underlying brain circuitry.</p> <p>19 Q. We can agree, though, that that</p> <p>20 article doesn't say ASD or ADHD, correct?</p> <p>21 A. Well, it certainly applies to</p> <p>22 ASD and ADHD. I think in this particular</p> <p>23 editorial they talk a little bit how these</p> <p>24 symptom domains cut across things like</p> <p>25 schizophrenia or bipolar disorder, or they</p>	<p style="text-align: right;">Page 345</p> <p>1 symptoms caused marked distress or interfered</p> <p>2 with functioning; otherwise they're just</p> <p>3 symptoms. Right?</p> <p>4 A. That's correct.</p> <p>5 Q. All right. Now, one of the</p> <p>6 things that you've mentioned a couple times</p> <p>7 are biological marker studies, right? And</p> <p>8 you cite Ji and Baker in your --</p> <p>9 A. Baker and Ji, yeah, biomarkers.</p> <p>10 Q. Right, biomarkers.</p> <p>11 And you think those are</p> <p>12 important, right?</p> <p>13 A. Well, they're a more -- they're</p> <p>14 a more direct measure of exposure.</p> <p>15 Q. Okay. And I noticed you cited</p> <p>16 Ji 2020, but did you review the earlier Ji</p> <p>17 study on maternal plasma?</p> <p>18 A. Let me see. It's possible that</p> <p>19 I reviewed more than one of the Ji studies.</p> <p>20 Let me just...</p> <p>21 I think I -- I think if they</p> <p>22 used similar cohort or approach, that I might</p> <p>23 have not cited every one of them, yeah.</p> <p>24 Q. So which is it? You didn't --</p> <p>25 you didn't cite it?</p>

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1 A. Well, I did cite it.

2 Q. Oh.

3 A. I cited the Ji 2020 article.

4 So are you referring to a

5 different year?

6 Q. I am.

7 A. Yeah, which year are you --

8 Q. 2018.

9 A. Right. Okay.

10 Q. Did you cite that?

11 A. No, because if the 2018 -- I'm

12 sorry. If the 2020 includes a similar

13 cohort, then I would cite the larger or more

14 comprehensive of the studies.

15 Q. Okay. But with Masarwa, you

16 cited 2018 and not the more current 2020,

17 right?

18 A. Well, again, the -- so the

19 20 -- the Masarwa -- the 2018 was the

20 meta-analysis. The 2020 examined one

21 particular issue of bias or confounding but

22 wasn't the original meta-analysis. So --

23 Q. Okay.

24 A. -- I cited the meta-analysis,

25 not the article that tested for one

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1 particular confounder.

2 Q. And your testimony now is that

3 Ji 2020 encapsulates Ji 2018, so you didn't

4 need to cite it, right?

5 A. I believe so.

6 Q. Okay. By the way, the

7 transdiagnostic theory you have on ASD and

8 ADHD is based on the shared feature of

9 hyperactivity, right?

10 A. No.

11 Q. Okay. The transdiagnostic

12 theory that you have connecting ADHD and A --

13 ASD doesn't replace the DSM, correct?

14 A. It doesn't re -- no, it

15 complements the DSM. So it's -- it's a -- it

16 maps on more closely to the underlying, you

17 know, circuitry or genetic, cellular --

18 because it -- it's more closely related to

19 the underlying defect, and the diagnosis is

20 more distal to the underlying defect.

21 Q. Dr. Hollander, is hyperactivity

22 a symptom of anything other than ASD and

23 ADHD?

24 A. Yes. I mean, hyperactivity can

25 be a symptom. It can be a symptom in other

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1 conditions.

2 Q. So your transdiagnosis theory

3 of --

4 A. And --

5 Q. Sorry.

6 A. And it -- and it can -- and it

7 can vary in severity as well. So it's a

8 symptom domain.

9 Q. Okay. So you agree that

10 hyperactivity is a symptom of much more than

11 just ASD and ADHD, correct?

12 A. Yeah, as a -- as a -- well,

13 first of all, so the notion of the

14 transdiagnostic is that the domain cuts

15 across different conditions.

16 Q. Right.

17 A. That's the sort of definition,

18 and it's not restricted to.

19 So, for example, I looked at

20 compulsivity like OCD, right? I saw that

21 there were a group of other disorders that

22 shared underlying features. So they had

23 similar clinical symptoms. They had similar

24 familial factors of transmission. They had

25 similar underlying brain circuitry. And as a

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1 result of that, the DSM was reorganized to

2 include a new chapter called obsessive

3 compulsive and related disorders.

4 And the reason that that

5 chapter in the DSM was organized was because

6 there was a common transdiagnostic symptom

7 domain that cut across all of the different

8 conditions that are now listed in the DSM-5.

9 Q. Okay. Dr. Hollander, if

10 acetaminophen causes a symptom domain like

11 hyperactivity, shouldn't it cause, by your

12 logic, every -- not just autism and ADHD, but

13 anything for which hyperactivity is a

14 symptom?

15 A. Well, again, you know, these

16 conditions are pretty heterogeneous, and they

17 include multiple different symptom domains.

18 Those symptom domains, you know, can cut

19 across different conditions.

20 There are other symptom domains

21 as well that can co-occur or shape the

22 expression of the disorder.

23 Q. According to Dr. Hollander --

24 A. And that -- well, I'm sorry,

25 just let me finish.

<p style="text-align: right;">Page 350</p> <p>1 So that APAP, or acetaminophen, 2 can be a causal factor in causing a symptom 3 domain. That doesn't mean, you know, that 4 it's the only factor causing that symptom 5 domain. And clearly there can be other 6 factors or combinations that come together to 7 get the full expression of the condition. 8 So -- but it -- if APAP 9 exposure affects, through the process of 10 neurodevelopment, a key brain circuitry, and 11 if that brain circuitry regulates that 12 symptom domain, then impacting that brain 13 circuitry would be associated with the 14 development of that symptom domain across 15 other conditions. 16 However -- but here's the 17 however also. It also depends on like the 18 timing of the exposure and the dose of the 19 exposure, because you may impact -- you may 20 create a -- you may impact or dysregulate a 21 particular circuit at a particular time of 22 exposure or dosage of the exposure but not 23 affect that circuitry with a different type 24 of an exposure. 25 But that exposure at a</p>	<p style="text-align: right;">Page 352</p> <p>1 timing is important and the dose is 2 important. 3 What is the important timing 4 for causation on autism? 5 A. Well, I mean, the best estimate 6 is exposure during the second and third 7 trimester. 8 Q. Okay. And when -- according to 9 Dr. Hollander, when is the timing to treat -- 10 to cause ADHD? 11 A. The second and third trimester. 12 Q. Okay. So it's the same. 13 According to Dr. Hollander, 14 what does acetaminophen cause other than ADHD 15 and autism? 16 A. Well, I mean, it can cause 17 liver failure. So, I mean, it really depends 18 on the dosage and the timing. 19 Q. Okay. 20 A. It could cause skin reactions. 21 I mean, it really depends on the dosage and 22 the timing. 23 Q. Dr. Hollander, when a pregnancy 24 is exposed to acetaminophen in the second and 25 third trimester -- second or third trimester,</p>
<p style="text-align: right;">Page 351</p> <p>1 particular timing that affects the underlying 2 circuitry of development would create those 3 symptoms expressed across different 4 conditions. 5 Q. Dr. Hollander, is IQ a symptom 6 domain for ASD? 7 A. No. 8 Q. Is IQ a symptom domain for 9 ADHD? 10 A. No. 11 Q. According to Dr. Hollander, 12 does acetaminophen cause major congenital 13 malformation? 14 A. No. 15 Q. According to Dr. Hollander, 16 does acetaminophen cause neural tube defects? 17 A. Usually no. 18 Q. Does acetaminophen ever cause 19 neural tube defects, according to 20 Dr. Hollander? 21 A. No. It causes more subtle 22 kinds of symptoms than major neural tube 23 defects. 24 Q. Okay. And you -- 25 Dr. Hollander, you just testified that the</p>	<p style="text-align: right;">Page 353</p> <p>1 what outcomes in the fetus can acetaminophen 2 cause, according to Dr. Hollander, other than 3 ASD and ADHD? 4 A. Well, I mean, it can impair 5 circuits such as frontostriatal circuits and 6 frontolimbic circuits that can present with 7 set switching, executive function-type 8 problems and impulsivity/hyperactivity. 9 Q. And, Dr. Hollander, you have no 10 direct human evidence of that. Your 11 testimony you just -- you just gave is based 12 on animal studies, correct? 13 A. No. 14 Q. Okay. What direct human 15 evidence do you have on impairing those exact 16 circuits? 17 A. Well, the Baker study used 18 functional MRI as a measure of outcome. So 19 they used a direct measure of exposure, 20 meconium, to determine the dose-response 21 relationship, and they used a direct measure 22 of outcome, which is functional MRI. And 23 they determined that there was a relationship 24 between exposure and hyperactivity and 25 hypoactivity of those circuits.</p>

<p>Page 354</p> <p>1 Q. Dr. Hollander, other than --</p> <p>2 how many patients were -- received an MRI in</p> <p>3 Baker?</p> <p>4 A. I'll have to take a look at it</p> <p>5 to get the exact number.</p> <p>6 Q. Was it a lot?</p> <p>7 A. Well --</p> <p>8 MR. DOVEL: Objection. Form.</p> <p>9 THE WITNESS: I -- it would</p> <p>10 have been a subgroup of the overall</p> <p>11 amount. So there were 345 subjects</p> <p>12 overall in the study, and a subgroup</p> <p>13 of that received a functional MRI.</p> <p>14 QUESTIONS BY MR. MURDICA:</p> <p>15 Q. Right.</p> <p>16 And it's not your testimony</p> <p>17 that the subjects who had their meconium</p> <p>18 sampled was direct human evidence of</p> <p>19 interference with those pathways, right?</p> <p>20 A. No. All that was doing was</p> <p>21 it's a more direct measure of the exposure.</p> <p>22 Q. Okay. Other than the MRIs on</p> <p>23 however many subjects were -- had an MRI</p> <p>24 measurement in Baker, do you have -- are you</p> <p>25 relying on any other direct human evidence</p>	<p>Page 356</p> <p>1 neuroimaging measures.</p> <p>2 So there's a -- there's a lot</p> <p>3 of information about underlying brain</p> <p>4 circuitry and these clinical conditions</p> <p>5 linked to these diagnoses, and there's a lot</p> <p>6 of information relating to circuits that are</p> <p>7 involved in the -- you know, cognitive</p> <p>8 features that are assessed by these outcome</p> <p>9 measures. So I'm also relying on that</p> <p>10 literature as well.</p> <p>11 Q. Dr. Hollander, on Exhibit 54,</p> <p>12 which are Dr. Baccarelli's tables that you're</p> <p>13 relying on, the only -- if you look through</p> <p>14 them, the only measure that you rely on for</p> <p>15 direct evidence of circuitry in the brain is</p> <p>16 the Baker subset, not any of the other</p> <p>17 studies, correct?</p> <p>18 A. Well, I would -- I would have</p> <p>19 to repeat myself again in that many of these</p> <p>20 outcome measures that have been tested in</p> <p>21 these different cohorts have also been</p> <p>22 studied and correlated with in neurocognitive</p> <p>23 features and brain circuitry.</p> <p>24 However, in the studies that</p> <p>25 link exposure and outcome directly, yeah, the</p>
<p>Page 355</p> <p>1 that acetaminophen allegedly interferes with</p> <p>2 that signaling in the fetus?</p> <p>3 A. Well, that -- I mean, it kind</p> <p>4 of gets to the experiment issue. And there</p> <p>5 were ethical issues in terms of dosing women</p> <p>6 with acetaminophen and then doing imaging on</p> <p>7 the offspring, so that hasn't been conducted.</p> <p>8 But I guess animal models would</p> <p>9 be a good way to be able to do that</p> <p>10 experiment, actually, and that's what's been</p> <p>11 done.</p> <p>12 Q. And my question was on human</p> <p>13 data.</p> <p>14 The only direct human evidence</p> <p>15 you're relying on for what we're talking</p> <p>16 about right now was the subset of Baker that</p> <p>17 had the MRIs, correct?</p> <p>18 A. Well, I am relying on that.</p> <p>19 That's what comes to my mind now.</p> <p>20 I guess I'm also relying on all</p> <p>21 of the other, you know, outcome measures that</p> <p>22 were used, whether they were diagnostic</p> <p>23 outcome measures or scales, and then my</p> <p>24 understanding of the correlation between</p> <p>25 those different measures and other</p>	<p>Page 357</p> <p>1 only -- my understanding, the only measure</p> <p>2 that currently exists in terms of like</p> <p>3 functional brain circuitry is the Baker</p> <p>4 study.</p> <p>5 Q. And other than ADHD and ASD --</p> <p>6 this is how we got on this topic -- what else</p> <p>7 can acetaminophen cause in the fetus?</p> <p>8 A. Well, it can also be associated</p> <p>9 with other neurodevelopmental problems.</p> <p>10 Q. Okay. And have you done an</p> <p>11 analysis on those? A causal analysis?</p> <p>12 A. Yes. I have discussed that,</p> <p>13 and then I also have relied on</p> <p>14 Dr. Baccarelli, who has also done a separate</p> <p>15 navigation weight-of-the-evidence analysis</p> <p>16 for neurodevelopment, and also has organized</p> <p>17 that material as it relates to exposure and</p> <p>18 other neurodevelopmental outcomes.</p> <p>19 Q. Is acetaminophen selective at</p> <p>20 all for neurodevelopmental outcomes, or does</p> <p>21 it cause all -- all neuro -- all bad</p> <p>22 neurodevelopmental outcomes, I guess I should</p> <p>23 say?</p> <p>24 A. No, I wouldn't say that it</p> <p>25 doesn't cause everything as it relates to --</p>

<p style="text-align: right;">Page 358</p> <p>1 and as I mentioned again, it doesn't -- so it</p> <p>2 can affect the liver and it can affect the</p> <p>3 skin. So it doesn't only affect</p> <p>4 neurodevelopment, although in the setting of</p> <p>5 maternal usage, it can be associated with</p> <p>6 different neurodevelopmental outcomes.</p> <p>7 It's not associated with neural</p> <p>8 tube defects. It's not associated with</p> <p>9 severe mental retardation.</p> <p>10 It is associated with these</p> <p>11 more subtle symptoms that cut across ASD and</p> <p>12 ADHD and other neurodevelopmental disorders,</p> <p>13 and is manifest by executive function set</p> <p>14 switching problems as well as impulsivity and</p> <p>15 hyperactivity.</p> <p>16 Q. But you go beyond the symptoms,</p> <p>17 right? You're saying -- Dr. Hollander is</p> <p>18 here telling the world that acetaminophen</p> <p>19 causes essentially every adverse neurological</p> <p>20 outcome in the fetus when the mother is</p> <p>21 exposed during the second or third trimester</p> <p>22 of pregnancy, correct?</p> <p>23 A. No.</p> <p>24 Q. Okay. But for sure,</p> <p>25 Dr. Hollander is telling the world that</p>	<p style="text-align: right;">Page 360</p> <p>1 A. -- relating to that.</p> <p>2 Q. Sure. And I'm going to mark it</p> <p>3 in a second.</p> <p>4 But did you consider discordant</p> <p>5 results in your analysis between the two</p> <p>6 outcomes?</p> <p>7 A. Yes.</p> <p>8 Q. Okay. And to the extent there</p> <p>9 were discordant results, it didn't impact</p> <p>10 your conclusion on causation as to both,</p> <p>11 correct?</p> <p>12 MR. DOVEL: Objection. Form.</p> <p>13 THE WITNESS: Well, I</p> <p>14 acknowledged the discordant results.</p> <p>15 I formed my opinion based on the</p> <p>16 totality of the evidence.</p> <p>17 QUESTIONS BY MR. MURDICA:</p> <p>18 Q. Okay. And you've definitely</p> <p>19 seen Ji 2018 before today, right?</p> <p>20 A. I believe so, yes.</p> <p>21 (Hollander Exhibit 61 marked</p> <p>22 for identification.)</p> <p>23 QUESTIONS BY MR. MURDICA:</p> <p>24 Q. Okay.</p> <p>25 A. Well, let me just take a look</p>
<p style="text-align: right;">Page 359</p> <p>1 acetaminophen exposure can cause ADHD and</p> <p>2 autism in the child, right?</p> <p>3 A. Yeah. Exposure to</p> <p>4 acetaminophen can be a causal factor in the</p> <p>5 development of ASD and ADHD and other</p> <p>6 neurodevelopmental disorders.</p> <p>7 Q. Okay. And did you see when you</p> <p>8 looked at Ji, the earlier Ji study, that --</p> <p>9 and it was a biomarker. It was maternal</p> <p>10 plasma.</p> <p>11 Did you see that Ji found an</p> <p>12 association with one of the outcomes but not</p> <p>13 the other? Do you remember that?</p> <p>14 A. I think I recall that, yes.</p> <p>15 Q. Okay. And that is not</p> <p>16 concordant, right?</p> <p>17 That does not fit your theory</p> <p>18 for acetaminophen to cause one of ADHD and</p> <p>19 autism and not the other, correct?</p> <p>20 MR. DOVEL: Objection. Form.</p> <p>21 THE WITNESS: I guess I'd have</p> <p>22 to look at the manuscript in order to</p> <p>23 be able to offer an opinion --</p> <p>24 QUESTIONS BY MR. MURDICA:</p> <p>25 Q. Sure.</p>	<p style="text-align: right;">Page 361</p> <p>1 and just make sure that I -- hold on one</p> <p>2 second in terms of materials considered.</p> <p>3 Yeah, that's -- it is included</p> <p>4 in my materials considered, both the 2018 and</p> <p>5 the 2020.</p> <p>6 Q. You now have in front of you</p> <p>7 what's been marked as Exhibit 61.</p> <p>8 Do you see it?</p> <p>9 A. Yes.</p> <p>10 Q. Do you recognize that as a</p> <p>11 study by Yuelong Ji?</p> <p>12 A. Yes.</p> <p>13 Q. Do you see that it's not the</p> <p>14 2020 study that you have cited in your</p> <p>15 report?</p> <p>16 A. Well, I see that it's the 2018</p> <p>17 study that's cited in my materials</p> <p>18 considered.</p> <p>19 Q. Right.</p> <p>20 This is not the Ji 2020 study,</p> <p>21 right? They're different.</p> <p>22 A. It's a different publication.</p> <p>23 Q. This is a maternal biomarker</p> <p>24 study, though, right?</p> <p>25 A. Well, it's part of the Boston</p>

<p style="text-align: right;">Page 362</p> <p>1 birth cohort, so it's the same birth cohort.</p> <p>2 Q. Do you know the difference</p> <p>3 between Ji 2018 and Ji 2020?</p> <p>4 A. Well, I can tell you that</p> <p>5 the -- this report is 1,180 children in the</p> <p>6 Boston birth cohort, and the Ji 2020 is -- so</p> <p>7 the -- I mean, they're measuring different</p> <p>8 things, so the -- you know, the Ji is looking</p> <p>9 at -- the 2020 is cord blood fetal blood, and</p> <p>10 the 2018 is as you mentioned.</p> <p>11 Q. Right.</p> <p>12 So, Dr. Hollander, they are</p> <p>13 different, right? They're different</p> <p>14 biomarkers?</p> <p>15 A. They're different biomarkers.</p> <p>16 Q. Yeah.</p> <p>17 And in your rebuttal report,</p> <p>18 when you listed the biomarker studies, you</p> <p>19 only cited Ji 2020 and Baker, correct?</p> <p>20 A. In my rebuttal in the section</p> <p>21 in biomarkers, yes, I included those two.</p> <p>22 Q. And that's because the results</p> <p>23 of this don't fit your theory, right?</p> <p>24 A. No, not necessarily.</p> <p>25 Q. Okay. Let me know when you are</p>	<p style="text-align: right;">Page 364</p> <p>1 about time, why ask that question?</p> <p>2 You know whether it's in his rebuttal</p> <p>3 or not.</p> <p>4 You want him to spend time</p> <p>5 looking through it?</p> <p>6 MR. MURDICA: I think he should</p> <p>7 know what's in his reports and not, so</p> <p>8 I got to ask the question.</p> <p>9 MR. DOVEL: Okay.</p> <p>10 THE WITNESS: Okay. Well,</p> <p>11 so --</p> <p>12 QUESTIONS BY MR. MURDICA:</p> <p>13 Q. Okay. So you've reviewed it.</p> <p>14 You reviewed it before today, right,</p> <p>15 Dr. Hollander?</p> <p>16 A. I have seen it before, and I've</p> <p>17 done a quick review of it now.</p> <p>18 Q. And you'll take -- well, I will</p> <p>19 represent to you that it's not in your report</p> <p>20 or your rebuttal report or your amended</p> <p>21 report. So at some point if that's true, you</p> <p>22 decided that you didn't need to cite it,</p> <p>23 right?</p> <p>24 A. Right. I don't think it is</p> <p>25 informative with regards to -- so, I mean,</p>
<p style="text-align: right;">Page 363</p> <p>1 ready to acknowledge that the outcome for</p> <p>2 ADHD and ASD are discordant when they studied</p> <p>3 maternal cord blood. Sorry, maternal plasma.</p> <p>4 It might help you, Doctor, if</p> <p>5 you look at Table 2 on page 7 of 15.</p> <p>6 Are you ready for a question,</p> <p>7 Doctor?</p> <p>8 A. Could I have one more minute --</p> <p>9 Q. Yeah.</p> <p>10 A. -- to just put this into</p> <p>11 context and understand it?</p> <p>12 Q. Because I don't want to get</p> <p>13 into a spat about time, but this is in his</p> <p>14 reliance materials.</p> <p>15 A. Okay. Okay.</p> <p>16 Q. Okay. Dr. Hollander, you</p> <p>17 reviewed this before today, right?</p> <p>18 A. Yes, I have.</p> <p>19 Q. Okay. And you chose not to</p> <p>20 include it in your rebuttal report, right?</p> <p>21 A. I wonder if I -- I mean, I've</p> <p>22 seen this and thought about the issues. Let</p> <p>23 me just make sure that I haven't cited it at</p> <p>24 all in my rebuttal, so...</p> <p>25 MR. DOVEL: If you're worried</p>	<p style="text-align: right;">Page 365</p> <p>1 the two points I would make. One is, there</p> <p>2 was no effect in the ASD.</p> <p>3 The second is, this is</p> <p>4 suggesting that there's some kind of a</p> <p>5 maternal factor associated with usage, right?</p> <p>6 Because it's occurring in maternal blood</p> <p>7 postpartum.</p> <p>8 So it gets back to the same</p> <p>9 issue there as to whether or not, you know,</p> <p>10 there's some kind of a maternal or genetic or</p> <p>11 familial factor that influences the usage</p> <p>12 that relates to the outcome.</p> <p>13 Q. Okay. Dr. Hollander, one of</p> <p>14 the reasons you just said you didn't include</p> <p>15 it is because there's no significant finding</p> <p>16 as to ASD, correct?</p> <p>17 A. Well, there is no finding with</p> <p>18 regards to ASD. I see that.</p> <p>19 I see that there are some</p> <p>20 findings as it relates to different models in</p> <p>21 terms of acetaminophen burden.</p> <p>22 Q. If you look at Table 2, Doctor,</p> <p>23 there's nothing significant under any model</p> <p>24 with respect to ASD or other DD, right?</p> <p>25 A. On that table, yeah.</p>

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1 Q. Those are the outcomes, right?

2 This is -- it's titled "The

3 association between maternal acetaminophen

4 metabolites and the risk of ADHD diagnosis,

5 ASD diagnosis or other developmental delay

6 diagnosis in offspring."

7 Right?

8 A. But the -- I mean, the issue

9 here is a particular plasma biomarker that's

10 measured a few days after delivery.

11 Q. Okay. So to you, to

12 Dr. Hollander, this biomarker study is not

13 informative on whether acetaminophen causes

14 autism and ADHD in offspring, correct?

15 A. Well, it's addressing whether

16 or not there's a particular familial or

17 genetic confounder that could be a factor in

18 terms of understanding the relationship

19 between APAP and ADHD.

20 Q. Dr. Hollander, do you know why

21 there were discordant findings between ADHD

22 and ASD?

23 MR. DOVEL: Objection. Form.

24 THE WITNESS: Well, let's see

25 if the authors address that.

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1 QUESTIONS BY MR. MURDICA:

2 Q. Without having to go back and

3 read it, you don't know sitting here right

4 now --

5 A. I don't recall it off -- I

6 mean, you're asking me to comment on the

7 findings of this article.

8 Q. Right.

9 A. So I'd be able to comment on

10 the findings of the article, but I need to be

11 able to read it.

12 Q. Right.

13 It was on your review

14 material -- your materials reviewed before

15 you rendered your opinions here, correct,

16 Doctor?

17 A. It is listed in the materials

18 considered.

19 Q. Okay. For Ji 2020, Doctor, you

20 know that the cord -- the biomarker was cord

21 blood, right?

22 A. That's correct.

23 Q. And the cord blood was

24 reflecting what was in the cord blood burden

25 as of birth, right? The time of birth?

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1 A. It reflects fetal blood supply

2 at the time of birth.

3 Q. Right.

4 And that was one snapshot in

5 time at the time of birth, correct?

6 A. It's one -- yes, it's collected

7 at one time period. It's not collected

8 throughout the pregnancy.

9 Q. Right.

10 And that one day, the couple

11 hours before birth, is not the only window

12 where the fetus is susceptible to

13 influenced-cause ASD and ADHD, correct?

14 A. Well, that -- that's correct.

15 Q. Okay.

16 A. I mean, the fetus would be

17 susceptible to exposure before that one-day

18 window.

19 Q. And the only measure in Ji 2020

20 is that one-day window at birth, correct?

21 A. That's -- that's one measure,

22 right.

23 Q. Okay. And in your report,

24 you're not critical of that one measure as a

25 biomarker. In fact, you think it's very

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1 important, that one measure at the time of

2 birth, correct?

3 A. Well, it does show a

4 dose-response relationship as it relates to

5 acetaminophen exposure during pregnancy.

6 Q. Okay. And Ji 2018 --

7 A. Yeah.

8 Q. -- you've disregarded because

9 it's one snapshot of exposure in the

10 peripartum period, correct?

11 A. Yeah. Well, it's not an

12 exposure during pregnancy.

13 MR. MURDICA: Okay. I'd like

14 to take a break so that I can save my

15 last 15 minutes and figure out exactly

16 what we're going to do with it. Just

17 need five minutes.

18 Thank you, Doctor. I'll be

19 right back.

20 THE WITNESS: Okay.

21 VIDEOGRAPHER: The time right

22 now is 5:59 p.m., and we're off the

23 record.

24 (Off the record at 5:59 p.m.)

25 VIDEOGRAPHER: The time right

<p style="text-align: right;">Page 370</p> <p>1 now is 6:07 p.m. We're back on the 2 record. 3 QUESTIONS BY MR. MURDICA: 4 Q. Dr. Hollander, are you ready to 5 proceed? 6 A. Yes, I am. 7 Q. Okay. You mentioned earlier 8 about conducting animal studies. 9 Do you remember that testimony? 10 A. I mentioned animal studies. 11 I'm not sure what you're referring to -- 12 Q. Dr. Hollander -- oh, sorry. 13 I thought that you said that 14 you've conducted animal studies before. 15 A. I have, yeah. 16 Q. All right. Not on 17 acetaminophen, right? 18 A. No. 19 Q. But you've conducted animal 20 studies and observed -- and observed 21 behaviors in the rodents that you ascribe to 22 different neurodevelopmental outcomes, right? 23 A. Yes. I mean, animal studies 24 are important because they were a way for me 25 to select compounds for therapeutic trials,</p>	<p style="text-align: right;">Page 372</p> <p>1 A. I'm not familiar with that 2 particular test. I could posit a guess, but 3 I'm not sure. 4 Q. Okay. Are you familiar with 5 the pup ultrasonic vocalization test? 6 A. Yes. 7 Q. Okay. And why don't you tell 8 us how that test is conducted. 9 A. Well, that's a kind of test 10 where you separate, I guess, a pup from the 11 mother, and then the pup protests with 12 ultrasonic vocalizations. 13 Q. Okay. And would -- 14 Dr. Hollander, would an increase or a 15 decrease in vocalization be evidence of 16 autism? 17 A. I guess a decrease in the 18 vocalizations would be associated with an 19 impairment in the social domain. 20 Q. Okay. So your answer to that 21 is decrease in vocalization? 22 A. Yes. If there's an impairment 23 in vocalizations when you separate the pup 24 from the mother, that would suggest social 25 deficits which would be associated with</p>
<p style="text-align: right;">Page 371</p> <p>1 actually. And if a compound can be effective 2 in an animal model of autism, well, then that 3 would be important to then give you support 4 to consider a trial on humans. 5 Q. Dr. Hollander, tell us what the 6 scent marking test is. 7 A. The scent marking test? 8 Q. Yes. 9 A. I'm not sure what you're 10 referring to in terms of the scent marking 11 test. 12 Q. Okay. Are you familiar with 13 the rodent animal study for -- that's scent 14 marking for neurodevelopmental outcomes? 15 A. I think I do in terms of sort 16 of -- yeah. 17 Q. Okay. 18 A. It's not a -- that's not a 19 standard model that I rely on in terms of 20 sort preclinical testing for compounds for 21 therapeutic trials. 22 Q. Dr. Hollander, in the scent 23 marking test, would increase or decrease of 24 scent be -- of scent marking be evidence of 25 autism?</p>	<p style="text-align: right;">Page 373</p> <p>1 autism model. So it looks at a particular 2 symptom domain within -- relevant to autism. 3 Q. Okay. And, Dr. Hollander, are 4 you familiar with the whole board explanation 5 test? Exploration test? 6 A. Well, I'm familiar with things 7 like the open field exploration test. 8 Q. Okay. How about the marble 9 burying test? Are you familiar with that? 10 A. That, I'm familiar with. 11 Q. Okay. In your rebuttal report 12 at page 35, you are talking about the Carey 13 study. 14 Do you see that on page 35? 15 A. Ji claimed the Carey study was 16 not addressed, is that what you're referring 17 to? 18 Q. Yeah, that's part of it. Yep. 19 In there. 20 A. Okay. 21 Q. And you -- and you cite it? 22 A. Yeah. 23 Q. You're relying on Carey for the 24 hypothesis that oxidative stress is a 25 biomarker for ASD outcome, right?</p>

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1 A. Well, I mean, as discussed,
 2 it's a mechanism study, right.
 3 Q. Right.
 4 A. And it doesn't go all the way
 5 from mechanism to disorder, but it's a step
 6 in the link.
 7 Q. And is it -- is it your
 8 testimony that Carey supported the link in
 9 the mechanism?
 10 A. It supports the link, and the
 11 issue is, well, if you adjust for
 12 confounders, well, the strength of the
 13 association decreases based on the sample
 14 size, but the odds ratio is still above 2.
 15 So there's still a strong relative risk, but
 16 that because of the sample size, it doesn't
 17 reach statistical significance.
 18 Q. Okay. And is that the best
 19 evidence you have, Doctor?
 20 MR. DOVEL: Objection. Form.
 21 QUESTIONS BY MR. MURDICA:
 22 Q. Of your mechanism -- of your
 23 oxidative stress mechanism?
 24 A. That's one piece of evidence in
 25 support of that.

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1 Q. It's the only piece of evidence
 2 you have in a human being, correct?
 3 MR. DOVEL: Objection. Form.
 4 THE WITNESS: Well, it's a --
 5 it's a piece of evidence in human
 6 beings that shows a strong relative
 7 risk between oxidized glutathione and
 8 ASD, that it is a study that's
 9 underpowered. And so when you start
 10 to adjust for some confounders, the
 11 relative risk persists, but the
 12 statistical significance goes away.
 13 (Hollander Exhibit 62 marked
 14 for identification.)
 15 QUESTIONS BY MR. MURDICA:
 16 Q. Okay. Let's see if that's
 17 true. We're going to mark this as
 18 Exhibit 62.
 19 A. Well, and I guess maybe just to
 20 contradict also what you said, it's not
 21 the -- it's not the only evidence, and so I
 22 also cite the Anand study as well.
 23 Q. Got it right here, Doctor.
 24 A. Okay.
 25 Q. That's next.

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1 A. Excellent.
 2 Q. If we have time.
 3 If you could please look at
 4 what's been marked as Exhibit 62, you have in
 5 front of you the Carey study, correct?
 6 A. Yes.
 7 Q. 2022. That's what you cited in
 8 your rebuttal report, right?
 9 A. Yes.
 10 Q. I'd like you to turn to the
 11 conclusions and just read the first sentence.
 12 You recognize Carey's
 13 conclusion, do you not, Dr. Hollander, that
 14 overall they did not observe strong
 15 associations between maternal markers of
 16 oxidative stress in the late second and third
 17 trimester and ASD-related traits, right?
 18 A. That's what the sentence says.
 19 Q. Okay. And the second and third
 20 trimesters are -- that's your key window that
 21 you just testified to, right?
 22 A. That is an important window.
 23 Q. Okay. So you just said you
 24 think it's strong, and the authors said they
 25 did not observe a strong association.

Page 377

1 So that you disagree with the
 2 conclusion of Exhibit 62, correct?
 3 A. Well, I mean, again, as a -- as
 4 an elevated odds ratio, it's -- when
 5 adjusting for different confounders and
 6 because of the sample size, you lose the
 7 statistical significance.
 8 Q. All right. In any event,
 9 Doctor, you're relying on --
 10 A. And by the way, also, just to
 11 continue with that thought, really.
 12 So what they are observing is
 13 these -- this relationship between the traits
 14 and this measure of oxidative stress. So
 15 that's very interesting also.
 16 Q. Okay. That's interesting. But
 17 at the end of the day, the conclusion of
 18 Carey does not support that there's a strong
 19 association between oxidative stress and the
 20 outcome of autism spectrum disorder, correct?
 21 MR. DOVEL: Objection. Form.
 22 THE WITNESS: Well, there is --
 23 there is -- they're saying that this
 24 is suggestive evidence and that
 25 further work should be conducted.

<p style="text-align: right;">Page 378</p> <p>1 QUESTIONS BY MR. MURDICA:</p> <p>2 Q. Okay. And the other study that</p> <p>3 you mentioned is Anand, right, Doctor?</p> <p>4 A. That's right.</p> <p>5 Q. Is that one any better for you,</p> <p>6 do you think?</p> <p>7 A. I'm happy to review that with</p> <p>8 you.</p> <p>9 Q. Okay. I just -- before you</p> <p>10 review it with me and I show you that it's</p> <p>11 not, I want to know your opinion as to</p> <p>12 whether that's helpful to your opinions.</p> <p>13 Anand.</p> <p>14 MR. DOVEL: Objection. Form.</p> <p>15 THE WITNESS: Well, I mean, it</p> <p>16 does suggest that higher</p> <p>17 concentrations are associated with</p> <p>18 ADHD diagnosis at an odds ratio of</p> <p>19 2.1, is a marker of oxidative stress</p> <p>20 in cord plasma was associated with a</p> <p>21 higher odds of ADHD.</p> <p>22 QUESTIONS BY MR. MURDICA:</p> <p>23 Q. Okay. That's what you believe</p> <p>24 it concludes, right?</p> <p>25 A. That's an interpretation of the</p>	<p style="text-align: right;">Page 380</p> <p>1 Q. Okay.</p> <p>2 A. And I also discussed that with</p> <p>3 Dr. Cabrera.</p> <p>4 Q. On the oxidative stress point,</p> <p>5 did you find any other articles involving</p> <p>6 human beings and acetaminophen?</p> <p>7 A. I guess I can -- to answer</p> <p>8 that, I could go to my --</p> <p>9 Q. Do you recall, sitting here</p> <p>10 today, Dr. Hollander, finding any articles</p> <p>11 other than the Anand and the Cabrera -- Anand</p> <p>12 and Carey?</p> <p>13 A. Well, I see that the Anand and</p> <p>14 the Carey are both mentioned in my rebuttal,</p> <p>15 and I could also look at my amended expert</p> <p>16 initial report and see if I cite additional</p> <p>17 references.</p> <p>18 Q. Okay. If you found anything</p> <p>19 else that you thought supported your opinion,</p> <p>20 it would be in the rebuttal or the initial</p> <p>21 report, correct, Doctor?</p> <p>22 A. It would be -- it would be in</p> <p>23 there. It would also be a wealth of</p> <p>24 information in the Cabrera report and</p> <p>25 rebuttal as well.</p>
<p style="text-align: right;">Page 379</p> <p>1 results, yes.</p> <p>2 Q. Okay. Did you come --</p> <p>3 Dr. Hollander, did you come up with Carey and</p> <p>4 Anand on your own?</p> <p>5 MR. DOVEL: Just a second.</p> <p>6 MR. MURDICA: He can answer</p> <p>7 that. If he didn't, I won't ask him</p> <p>8 if it came from counsel. I just need</p> <p>9 to know if he came up with it on his</p> <p>10 own.</p> <p>11 MR. DOVEL: Well, the way it's</p> <p>12 phrased, the Southern District of</p> <p>13 New York counts that as asking, so</p> <p>14 you're going to have to rephrase it.</p> <p>15 QUESTIONS BY MR. MURDICA:</p> <p>16 Q. Dr. Hollander, did you find the</p> <p>17 Anand article?</p> <p>18 A. Did I find the Anand article?</p> <p>19 Q. Yes.</p> <p>20 A. Yes, it popped up in my search,</p> <p>21 and I also discussed it with other experts</p> <p>22 such as Dr. Cabrera.</p> <p>23 Q. Okay. And did you find the</p> <p>24 Carey article?</p> <p>25 A. Yes.</p>	<p style="text-align: right;">Page 381</p> <p>1 Q. Are you relying, Doctor, on --</p> <p>2 are you relying on Dr. Cabrera for the</p> <p>3 biological -- the plausible biological</p> <p>4 mechanism aspect, or are you opining on that</p> <p>5 yourself?</p> <p>6 A. I've had the opportunity to</p> <p>7 speak with him, and I've had the opportunity</p> <p>8 to read his report and his rebuttal. I agree</p> <p>9 with that.</p> <p>10 I am relying on my own reading</p> <p>11 of the articles.</p> <p>12 Q. Okay. So your biological</p> <p>13 mechanism opinions stand on their own, and</p> <p>14 you don't need Dr. Cabrera. You're not</p> <p>15 relying on Dr. Cabrera, correct?</p> <p>16 A. Well, that's correct. I offer</p> <p>17 opinions with regards to plausible biological</p> <p>18 mechanism in my reports.</p> <p>19 Q. Okay. And you don't know which</p> <p>20 of those -- which mechanism is the most</p> <p>21 plausible biologic mechanism according to</p> <p>22 Dr. Hollander?</p> <p>23 A. According to Dr. Hollander?</p> <p>24 Q. Yes.</p> <p>25 A. Well, I think impact on the</p>

Page 382

1 endocannabinoid system is a very important --

2 Q. Okay.

3 A. -- mechanism. I do think that

4 oxidative stress is an important biological

5 mechanism. I think epigenetics is a very

6 important biological mechanism as well.

7 Q. And all three of those, you

8 believe, are causative between acetaminophen

9 exposure and the outcomes of ASD and autism,

10 right?

11 A. Well, all of them are plausible

12 biological mechanisms by which exposure to

13 acetaminophen can cause ADHD or ASD and

14 neurodevelopmental disorders.

15 (Hollander Exhibit 63 marked

16 for identification.)

17 QUESTIONS BY MR. MURDICA:

18 Q. Perfect.

19 Okay. We'll mark this as

20 Exhibit 63, please.

21 All right. This is the last

22 thing I'm going to be asking you about,

23 Doctor.

24 Dr. Hollander, you now have in

25 front of you Exhibit 63. This is the Anand

Page 383

1 study that you cited in your rebuttal report,

2 correct?

3 A. It's 2021. And 2021, it does

4 appear to be that. Yep.

5 Q. Okay. I'm just going to

6 direct -- in the interest of time, because

7 we're almost out of time, I'm going to direct

8 you to page 10 of 16 for my question, Doctor.

9 If you look at the second

10 paragraph under Discussion, it says, "These

11 findings are in opposition to our original

12 hypothesis that lower levels of amino acids

13 involved in the synthesis of glutathione may

14 explain the association between cord

15 acetaminophen and ADHD risk."

16 Did I read that correctly?

17 A. Well, you read the sentence,

18 yes.

19 Q. Okay. And do you disagree with

20 the sentence as it appears in the Anand

21 article?

22 A. Well, they're saying that

23 increasing cord methionine and glycine

24 partially statistically mediated the

25 association between cord acetaminophen levels

Page 384

1 greater than 50th percentile and childhood

2 ADHD diagnosis.

3 Q. And my question was, do you

4 disagree with the sentence as it appears in

5 the Anand article, the one that I read?

6 A. Well, there are -- they are

7 suggesting that they -- these findings are

8 different than what they originally

9 hypothesized.

10 Q. Okay. And do you disagree with

11 their findings, that they're not consistent

12 with what they hypothesized?

13 A. Well, they're finding something

14 that's a little bit different than what they

15 originally hypothesized.

16 Q. Okay. Dr. Hollander, I'm

17 really trying to be done with this here.

18 This is -- this is the last question I'm

19 asking.

20 Do you disagree that they did

21 not confirm their theory that oxidative

22 stress was the hypothesis to explain the

23 connection between cord acetaminophen and

24 ADHD risk?

25 A. The -- one thing that's

Page 385

1 interesting is they're finding certain things

2 that are mediators of the association.

3 Q. Are you able to answer my

4 question?

5 A. Well, if you look at their

6 conclusions, "the oxidative stress biomarker,

7 8-hydroxy-deoxyguanosine, were associated

8 with increased odds of childhood ADHD, and

9 further that these other measures were

10 partial mediators of the association between

11 higher levels of cord acetaminophen and

12 childhood ADHD."

13 Q. Dr. Hollander, my question

14 was --

15 A. "These results suggest that

16 oxidative stress mechanisms should be further

17 explored to understand the link between

18 perinatal acetaminophen exposure and risk of

19 childhood ADHD."

20 You know, it's not unusual that

21 you have a particular hypothesis, that you

22 have findings that you may modify or revise

23 your hypothesis according to the results. So

24 I find that appropriate.

25 Q. Dr. Hollander, did you

<p style="text-align: right;">Page 386</p> <p>1 accurately portray the results of Anand in 2 your rebuttal report? 3 A. Well, they're -- I mean, 4 they're saying here there's oxidative stress 5 biomarker is associated with the increased 6 odds of childhood ADHD and that -- yes, so I 7 think that that's accurate. 8 MR. MURDICA: Okay. If that's 9 what you think, that's fine. I have 10 no further questions. 11 CROSS-EXAMINATION 12 QUESTIONS BY MR. DOVEL: 13 Q. Sir, just keep that same 14 document out. 15 Defendants' counsel was asking 16 you about a particular sentence in Anand. 17 I'd like you to read yourself the very next 18 two sentences. 19 A. Okay. Could you please direct 20 me to the page and the -- 21 Q. Page 10. 22 A. Okay. 23 Q. Last paragraph. Sentences 2 24 and 3. 25 A. The sentence that begins, "This</p>	<p style="text-align: right;">Page 388</p> <p>1 Q. In your view, are the effects 2 reported here from acetaminophen burden on 3 ADHD and ASD discordant or concordant? 4 A. You know, as I was mentioning, 5 so there's an elevated odds ratio for a 6 relationship between acetaminophen burden and 7 ADHD that's, you know, elevated across a 8 number of different models. 9 The sample size is 188 10 individuals, and the p-values are all 11 statistically significant. 12 If you look at the same with 13 regards to the ASD, you know, the -- so the 14 overall rate is lower, and the -- so the 15 sample size is a lot lower. So it's only 44 16 as compared to, you know, a higher percentage 17 of the population and the bigger number for 18 ADHD. 19 So the odds ratio is pretty 20 similar, actually, across all of these 21 different models, whether it's ADHD or ASD. 22 But the p-values aren't statistically 23 significant, but the -- but the reason is 24 that the sample size is less than a quarter 25 of the size.</p>
<p style="text-align: right;">Page 387</p> <p>1 may suggest that"? 2 Q. And the one right above it. 3 A. Okay. 4 Q. The "however" -- 5 A. "However, elevated levels of 6 methionine, serine, glycine and glutathione 7 were significantly correlated with the 8 oxidative stress biomarker 9 8-hydroxy-deoxyguanosine. This may suggest 10 that potential disruption of the homeostasis 11 of glutathione synthesis by acetaminophen is 12 associated with increased oxidative stress." 13 Q. Is that conclusion consistent 14 or inconsistent with your opinions? 15 A. Well, that's consistent with my 16 opinions. 17 Q. Let's turn to Ji 2018, 18 Exhibit 61. 19 A. Yes. 20 Q. I'd like you to look at -- 21 let's start with Table 3. It's on page 8. 22 A. Okay. 23 Q. Do you see where it reports the 24 odds ratios for ADHD and ASD? 25 A. Yes, I do.</p>	<p style="text-align: right;">Page 389</p> <p>1 So the -- to some extent, 2 they're all elevated odds ratio, whether it's 3 in ASD or ADHD, so that's a concordance. But 4 the sample size is smaller, so the 5 statistical significance is not as strong. 6 Q. Dr. Baccarelli, in his rebuttal 7 report, has a discussion of comparing Ji 2018 8 and Ji 2020 where he concludes, "The Ji 2018 9 study, if anything, supports my conclusions 10 rather than refuting them." 11 Do you agree with that? 12 MR. MURDICA: Objection to 13 form. 14 QUESTIONS BY MR. DOVEL: 15 Q. Let me rephrase it. 16 He says, "The Ji 2018 study, if 17 anything, supports my conclusions rather than 18 refuting them." 19 MR. MURDICA: Objection to 20 form. 21 QUESTIONS BY MR. DOVEL: 22 Q. Let me ask my question. 23 Do you agree or disagree with 24 that statement? 25 MR. MURDICA: Objection to</p>

<p>Page 390</p> <p>1 form.</p> <p>2 THE WITNESS: I agree with that</p> <p>3 statement.</p> <p>4 QUESTIONS BY MR. DOVEL:</p> <p>5 Q. I'd like you to look at</p> <p>6 Exhibit 55. That's the Masarwa 2018 study.</p> <p>7 You were asked some questions</p> <p>8 about the adjustment in Masarwa for parental</p> <p>9 diagnosis of ASD or ADHD.</p> <p>10 Is adjusting for parental</p> <p>11 diagnosis something that would have an effect</p> <p>12 on showing the true association?</p> <p>13 MR. MURDICA: Objection. Form.</p> <p>14 THE WITNESS: Well, again, it's</p> <p>15 the same issue in terms of sort of</p> <p>16 genetic confounders. So if those</p> <p>17 genetic confounders affect the</p> <p>18 mechanism by which APAP exerts its</p> <p>19 effect or moderates that effect, then</p> <p>20 it would give you a false information</p> <p>21 with regards to the true association.</p> <p>22 QUESTIONS BY MR. DOVEL:</p> <p>23 Q. In your view, does Masarwa</p> <p>24 2018, which does not make that adjustment,</p> <p>25 provide a better estimate of the effects of</p>	<p>Page 392</p> <p>1 Does that sentence indicate</p> <p>2 that there was no information taken about</p> <p>3 when the medication was taken?</p> <p>4 MR. MURDICA: Objection to</p> <p>5 form.</p> <p>6 THE WITNESS: Well, so I see</p> <p>7 that there are different contacts, and</p> <p>8 this is talking about the first</p> <p>9 contact, what's covering the period</p> <p>10 where they're asking.</p> <p>11 But then there are other</p> <p>12 contacts, I guess, at 12 and 30 weeks,</p> <p>13 right?</p> <p>14 QUESTIONS BY MR. DOVEL:</p> <p>15 Q. Yeah, so I'm starting with the</p> <p>16 first contact.</p> <p>17 A. Okay.</p> <p>18 Q. Is it consistent with that</p> <p>19 sentence that the mothers would have given a</p> <p>20 report about the period from four weeks</p> <p>21 before pregnancy as well as a report about</p> <p>22 pregnancy?</p> <p>23 A. Well, it doesn't -- you know,</p> <p>24 it doesn't specify in that sentence</p> <p>25 whether -- so they're asking for that, but</p>
<p>Page 391</p> <p>1 acetaminophen as compared to the adjustment</p> <p>2 that's done in Masarwa 2020?</p> <p>3 MR. MURDICA: Object to form.</p> <p>4 THE WITNESS: Well, I mean,</p> <p>5 the answer is yes. I mean, if there</p> <p>6 are genetic or familial factors that</p> <p>7 again mediate or moderate the effect,</p> <p>8 then if you adjust for those factors,</p> <p>9 then it interferes with what the true</p> <p>10 association is.</p> <p>11 QUESTIONS BY MR. DOVEL:</p> <p>12 Q. Let's look at Exhibit 58, the</p> <p>13 supplementary material for Alemany.</p> <p>14 I want you to turn to page 5.</p> <p>15 We're going to talk about the description of</p> <p>16 the DNBC cohort in the second paragraph.</p> <p>17 Do you have that in front of</p> <p>18 you?</p> <p>19 A. Yes, I do.</p> <p>20 Q. The second sentence there says,</p> <p>21 "At the first contact, women filled out a</p> <p>22 form that included questions regarding any</p> <p>23 supplement in medication use covering the</p> <p>24 period from four weeks before pregnancy to</p> <p>25 the gestational of reporting."</p>	<p>Page 393</p> <p>1 they don't say whether or not they're asking</p> <p>2 about -- so they may be asking about it</p> <p>3 during that time period, but they may be</p> <p>4 recording it during -- for pregnancy or not</p> <p>5 during pregnancy.</p> <p>6 Q. If we look at the last</p> <p>7 sentence -- rather the last two sentences,</p> <p>8 does that indicate that in classifying</p> <p>9 mothers as users of acetaminophen during</p> <p>10 pregnancy, that it included use before</p> <p>11 pregnancy?</p> <p>12 MR. MURDICA: Objection to</p> <p>13 form.</p> <p>14 THE WITNESS: No, it doesn't.</p> <p>15 And so that's what I meant, is that</p> <p>16 this sentence is not in accord with</p> <p>17 the earlier sentence. So the --</p> <p>18 it's suggesting that when they</p> <p>19 classify the users, they're</p> <p>20 classifying the users based on whether</p> <p>21 or not they took acetaminophen during</p> <p>22 pregnancy or not.</p> <p>23 But they're not classifying the</p> <p>24 users -- they may have asked about</p> <p>25 that, but they may not have classified</p>

Page 394

1 them as using it during pregnancy.

2 QUESTIONS BY MR. DOVEL:

3 Q. If there were a study that had

4 included in its analysis maternal use before

5 pregnancy and had that -- and had lumped that

6 in with use during pregnancy, so that a use

7 of acetaminophen that would not cause autism

8 or ADHD was lumped in, would that then bias

9 the results towards the null?

10 MR. MURDICA: Objection to

11 form.

12 THE WITNESS: Yes, it would.

13 MR. DOVEL: No further

14 questions.

15 REDIRECT EXAMINATION

16 QUESTIONS BY MR. MURDICA:

17 Q. Okay. Staying on this exhibit.

18 Dr. Hollander, your

19 interpretation of what the DNBC cohort

20 counted as acetaminophen exposure is based on

21 the -- not based on what was collected in

22 the -- in the second line, but based on the

23 last line: Mothers were classified as users

24 of acetaminophen during pregnancy if they had

25 taken any dose of acetaminophen at any time

Page 395

1 up during pregnancy.

2 Right?

3 A. Well, it's consistent with

4 that, but it's also consistent with the idea

5 that -- so what -- it is consistent with that

6 sentence.

7 The earlier sentence doesn't --

8 so all it says is that they fill out a form.

9 The form includes questions. The -- but it

10 doesn't say how -- what exactly is on the

11 form or how the form is specified, whether it

12 asked questions about pregnancy use or use

13 four weeks before the pregnancy.

14 Q. Dr. Hollander, you know that

15 this is the cohort published in the Liew

16 studies, right?

17 A. Yes.

18 Q. You could -- you could have

19 gone -- before you just gave the answers to

20 your counsel that are wrong, you could have

21 gone, and should have gone as the expert

22 here, to the Liew studies and figured out the

23 correct answer, right?

24 A. There's nothing in the Liew

25 study that suggests -- and in fact, didn't we

Page 396

1 do that? I thought that we were looking at

2 the methods of the Liew study.

3 Q. I have time limited to the time

4 your counsel used, so --

5 A. Okay.

6 Q. -- I am not asking you to go

7 look now.

8 A. Okay.

9 Q. You know you could have gone to

10 look at how Liew collected data for DNBC,

11 correct?

12 A. That's right. And in the

13 methods, it didn't specify what you're

14 alleging.

15 Q. Okay. And you just, in

16 response to a question your counsel asked

17 you, said essentially that you disagree with

18 Masarwa's 2020 analysis of their own study,

19 right?

20 MR. DOVEL: Objection. Form.

21 THE WITNESS: No.

22 QUESTIONS BY MR. MURDICA:

23 Q. Okay. Didn't you say that

24 Masarwa's interpretation of bias in its 2020

25 study is incorrect? It's not how you would

Page 397

1 interpret the bias, right?

2 A. Well, let's take a look at that

3 again.

4 Q. You didn't look at it when your

5 counsel was asking you questions, right,

6 Doctor?

7 A. Well, I'm looking at it in

8 response to your question.

9 Q. Okay. And, Doctor, just for

10 the record, I want it to reflect that you

11 were able to answer the question just fine

12 when your counsel asked it, incorrectly, and

13 now you're taking time to look at the study.

14 MR. DOVEL: Well, as long as

15 we're making a record, it was a very

16 different question that I asked him

17 that you asked on a different subject

18 altogether.

19 QUESTIONS BY MR. MURDICA:

20 Q. Dr. Hollander?

21 A. Yes.

22 Q. You disagree with the

23 conclusions the authors of Masarwa 2020 drew

24 from their bias analysis, correct?

25 A. That's correct.

<p style="text-align: right;">Page 398</p> <p>1 Q. Okay. Back to DNBC cohort. 2 Plaintiffs' counsel asked you a 3 question about if prepregnancy exposures were 4 included. You testified that it would bias 5 the data to the null, and I think I 6 interpreted that as meaning Dr. Hollander 7 says it would make the association with 8 acetaminophen in the outcome study look 9 smaller. 10 Was that your testimony? 11 A. That misclassification would 12 bias to the null. 13 But also in examining the 14 methods of the manuscript itself doesn't 15 mention anything about that. And in 16 examining the supplement material that you 17 just showed me, it's clearly inconsistent 18 internally, and that the sentence, "Mothers 19 were classified as users of acetaminophen 20 during pregnancy if they had taken any dose 21 of acetaminophen at any time up during 22 pregnancy." 23 And that the earlier sentence 24 that seems to be contradictory to that is 25 actually -- it doesn't specifically specify.</p>	<p style="text-align: right;">Page 400</p> <p>1 you talked about earlier, counseling your 2 patients about medication during pregnancy, 3 do you think that pregnant women have any 4 concern about using pregnant -- medicine 5 during pregnancy more so than they did before 6 they're pregnant? 7 A. Could you rephrase that? 8 Q. Sure. 9 A. I'm not sure I understand that. 10 Q. When -- wouldn't a woman be 11 more likely to take a medication before she 12 knows she's pregnant than after she knows 13 she's pregnant? 14 A. I mean, it depends on the 15 symptom. 16 Q. Don't -- 17 A. And it also depends on the risk 18 versus benefit or the knowledge. 19 Q. You don't think women express 20 more concern about taking medication once 21 they know they're pregnant? 22 A. I think it depends on what's -- 23 what are the guidelines or the -- what people 24 are told in terms of whether medicines are 25 considered to be safe or not.</p>
<p style="text-align: right;">Page 399</p> <p>1 It's just telling you that they're asking 2 about that time period, but it's not telling 3 you that they're classifying that during that 4 time period. 5 Q. Dr. Hollander, forget about the 6 DNBC then. 7 You already agreed earlier, 8 four of them plainly say they counted 9 exposures 30 days during pregnancy, right? 10 For the cohorts. You already agreed to that. 11 A. Well, they are saying -- maybe 12 we should take a look at those sentences 13 again, just to be clear. 14 Q. Go ahead, Doctor. 15 A. Okay. 16 Q. Okay. Some of the cohorts 17 definitely counted exposures to acetaminophen 18 for the 30 days before pregnancy, correct? 19 A. Well, it -- in reading that, 20 there is -- there is a sentence that says 21 that. 22 Q. Okay. Assuming that the 23 cohorts do count exposure the month before 24 pregnancy, here's my question for you. 25 Based on your experience that</p>	<p style="text-align: right;">Page 401</p> <p>1 Q. Okay. So according to 2 Dr. Hollander, a woman, before she's pregnant 3 and after she knows she's pregnant, looks at 4 medication and putting medication into her 5 body the exact same way, correct? 6 A. It also depends on the 7 symptoms. So there are some women who get 8 symptoms during pregnancy. They wouldn't 9 have those symptoms beforehand. 10 So, well, yeah, they would be 11 more likely to take the medicine during 12 pregnancy than before if they're -- if 13 they're having more symptoms during the 14 pregnancy than before. 15 Q. Okay. Dr. Hollander, if there 16 is prepregnancy data included here, the use 17 is more likely -- use of acetaminophen is 18 more likely than during pregnancy, correct? 19 MR. DOVEL: Objection. Form. 20 THE WITNESS: Yeah. I guess 21 the issue again is whether or not the 22 symptoms and when are -- when are the 23 symptoms more likely so that women 24 will be taking medicine to deal with 25 the symptoms. And also, what are the</p>

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1 risks versus benefit understanding

2 with regards to the particular

3 medication.

4 QUESTIONS BY MR. MURDICA:

5 Q. Okay. And when we were talking

6 about Ji 2018, you stand by your testimony

7 that the peripartum exposure in the

8 peripartum -- sorry. The peripartum

9 biomarkers in the blood is irrelevant to the

10 analysis, despite the answers you gave to

11 plaintiffs' counsel, correct?

12 MR. DOVEL: Objection. Form.

13 THE WITNESS: Well, maybe you

14 can read back to me the statement that

15 you're asking me to consider whether

16 or not I stand by it.

17 QUESTIONS BY MR. MURDICA:

18 Q. Okay. I'm not going to go find

19 it, Dr. Hollander, but let me just ask it

20 this way.

21 A. Yeah.

22 Q. Prior to plaintiffs' counsel

23 asking you questions that you answered, did

24 you want to change any of your testimony that

25 you gave me before that?

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1 A. I think -- I think I would,

2 because I understand it a little bit better.

3 Yes.

4 Q. Okay. So you want to -- Ji,

5 which you reviewed before you rendered

6 opinions here, right? 2018?

7 A. Ji that I reviewed a while ago

8 and which you gave to me and I tried to

9 interpret it relatively quickly, but I didn't

10 really have time to evaluate it, yeah.

11 Now I would like to have a

12 better understanding, now that I've been able

13 to review the manuscript better.

14 Q. Well, we're out of time, so I

15 guess you're going to have to get the better

16 understanding after the deposition.

17 That was ten days ago when you

18 rendered your rebuttal report, right?

19 A. I'm not exactly sure how many

20 days.

21 Q. Does that sound about right?

22 July 28th?

23 A. Sounds about right.

24 MR. MURDICA: Okay. I have no

25 further questions.

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1 THE WITNESS: Okay.

2 MR. DOVEL: This is the

3 conclusion of our deposition.

4 THE WITNESS: Okay.

5 VIDEOGRAPHER: The time right

6 now is 6:48 p.m. We are off the

7 record.

8 (Deposition concluded at 6:48 p.m.)

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1 CERTIFICATE

2 I, CARRIE A. CAMPBELL, Registered

3 Diplomat Reporter, Certified Realtime

4 Reporter and Certified Shorthand Reporter, do

5 hereby certify that prior to the commencement

6 of the examination, Eric Hollander, M.D.,

7 DFAPA, FACNP, was duly sworn by me to testify

8 to the truth, the whole truth and nothing but

9 the truth.

10 I DO FURTHER CERTIFY that the

11 foregoing is a verbatim transcript of the

12 testimony as taken stenographically by and

13 before me at the time, place and on the date

14 hereinafter set forth, to the best of my

15 ability.

16 I DO FURTHER CERTIFY that I am

17 neither a relative nor employee nor attorney

18 nor counsel of any of the parties to this

19 action, and that I am neither a relative nor

20 employee of such attorney or counsel, and

21 that I am not financially interested in the

22 action.

23

24

25

CARRIE A. CAMPBELL,
 NCRA Registered Diplomat Reporter
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 Illinois Certified Shorthand Reporter
 #084-004229
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 Louisiana Certified Court Reporter
 #2021012
 Notary Public
 Dated: August 10, 2023

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INSTRUCTIONS TO WITNESS

Please read your deposition over carefully and make any necessary corrections. You should state the reason in the appropriate space on the errata sheet for any corrections that are made.

After doing so, please sign the errata sheet and date it. You are signing same subject to the changes you have noted on the errata sheet, which will be attached to your deposition.

It is imperative that you return the original errata sheet to the deposing attorney within thirty (30) days of receipt of the deposition transcript by you. If you fail to do so, the deposition transcript may be deemed to be accurate and may be used in court.

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ACKNOWLEDGMENT OF DEPONENT

I, _____, do hereby certify that I have read the foregoing pages and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheet.

Eric Hollander, M.D. DFAPA, FACNP DATE _____

Subscribed and sworn to before me this _____ day of _____, 20 ____.

My commission expires: _____

Notary Public

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